Using virtual reality to assess associations between paranoid ideation and components of social performance

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SYSTEMATIC REVIEW
EMPIRICAL RESEARCH PROJECT
SERVICE EVALUATION PROJECT

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1. Using virtual reality for the assessment and treatment of cognitive and behavioural processes associated with social functioning impairments in psychosis: A systematic review

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ABSTRACT

***Background*:** People with psychosis can experience significant social functioning impairments. Virtual reality (VR) can extend traditional assessment and treatment of social functioning impairments in an ecologically valid environment. VR assessments and treatments (either 'immersive' VR, using a head mounted display, or 'non-immersive' VR, using a 2D screen) are increasingly being evaluated in psychosis research. The aim of this systematic review was to evaluate whether VR can improve assessment and treatment of social functioning impairments in people with psychosis. ***Method*:** PsycINFO, MEDLINE, Embase, Web of Science, Cochrane Library, ProQuest, and Scopus were searched. The Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies method and tool was used to assess the quality of studies. ***Results*:** Database searching identified 2212 titles. A total of 105 studies were screened; 32 studies published between 2005 and 2015 were included in the review (12 immersive VR; 20 non-immersive VR). 75% of studies received an EPHPP global rating of strong. ***Discussion*:** VR has potential as a tool to improve assessment and treatment of both cognitive and behavioural components of social functioning impairments in people with psychosis. Treatment packages have focused on general social skills or job interview/vocational skills. Limitations such as small sample sizes, lack of large RCTs, lack of novel VR-specific results, cybersickness, and scope of studies and technology are discussed; and potential advantages of egocentric encoding enabled by immersive VR are explored.

KEYWORDS: virtual reality; psychosis; schizophrenia; social functioning; systematic review

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1. INTRODUCTION

1.1 Social functioning in psychosis

Social functioning has been defined as an individual's interactions with their environment and their ability to fulfil their role within environments such as work, social activities, and relationships with partners and family (Bosc, 2000). Social functioning impairments can be a long standing problem in people with psychosis (Addington et al., 2008; Swartz et al., 2007). They are associated with poor outcome and reduced activities of daily living, when compared with the general population (Viertiö et al., 2012). Furthermore, social functioning impairments are related to high prevalence of early life trauma (Stain et al., 2013); underpinned by neurocognitive deficits (Carrión et al., 2011; Mancuso et al., 2011); and are, in themselves, a risk factor for developing psychosis (Cornblatt et al., 2011). In general, the onset of psychosis is strongly associated with prolonged experiences of social isolation (Reininghaus et al., 2008), diminished social networks (Garety et al., 2001), and impairments in social cognition (Bertrand et al., 2007; Couture et al., 2006). In particular, there is evidence that social cognition mediates the relationship between cognitive and social functioning (Addington et al., 2006); and a chronic and prolonged experience of social defeat has been shown to increase the risk of schizophrenia (Selten & Cantor-Graae, 2005).

As a consequence, interventions that support social relationships, functioning, and performance in the context of psychosis have been shown to be instrumental to subjective recovery (Gayer-Anderson & Morgan, 2013; Tew et al., 2011) and to improving psychological wellbeing (Schrank et al., 2014). Similarly, family interventions have been shown to have an important role in the treatment of psychosis (Bird et al., 2010; Pilling et al., 2002). However, the presence of social anxiety, negative self-statements, and negative symptoms continue to provide obstacles to these interventions.

1.2 Virtual reality and social functioning

Virtual reality (VR) has been defined as ‘human immersion in a synthetic system’ (Seidel & Chatelier, 2013). VR technologies are considered to be a promising supplement to traditional psychotherapy. Computer-generated social environments simulate real experiences and trigger anxiety in similar ways to conventional exposure therapy, and at the same time they allow the therapist to manipulate the social environment and tailor it to the needs of the patient (Eichenberg & Wolters, 2012).

VR has been cited as the most fully developed, innovative emerging technology (Thornhill-Miller & Dupont, 2016) and is already employed in clinical practice to treat cognitive, emotional, and behavioural problems (Bohil et al., 2011; Gregg & Tarrier, 2007; Riva, 2005). Whereas

traditional psychological assessment methods employ self-report measures, video feedback, and role-play, which may have limited ecological validity, VR can provide ecologically valid therapeutic environments that enable clinicians to manipulate VR design and real-time environmental conditions (Parsons, 2011). Psychological assessment and treatment methods that employ VR have been shown to elicit cognitive, emotional and behavioural responses similar to those triggered by real situations, while virtual characters can be perceived as real human beings (Ku et al., 2006). VR provides researchers and clinicians with the facility to manipulate environmental triggers that elicit distress in people with mental health problems, potentially allowing them to learn to better manage their difficulties (Gregg & Tarrier, 2007; Riva, 2005).

Notable VR innovations in mental health include research and treatments in post-traumatic stress disorder (Gonçalves et al., 2012), anxiety disorders (Meyerbröker & Emmelkamp, 2010), specific phobias (Parsons & Rizzo, 2008), eating disorders (Brownley et al., 2007), depression (Falconer et al., 2016), and psychosis (Freeman, 2008; Veling et al., 2014). VR treatments for mental health conditions have focused prominently on social functioning impairments. The advantage of VR interventions has been to improve the ecological validity of existing methods of assessing social functioning. Unlike role plays and self-report measures, the ecological validity of VR is derived from the real time presentation and control of perceptual stimuli. In anxiety disorders, for example, VR exposure therapy has been shown to be a realistic and acceptable intervention. One study found VR exposure therapy effective for treating social fears, while improvement was maintained at one year follow-up (Anderson et al., 2013). In general, reviews have found that VR exposure elicits psychophysiological fear reactions in patients and healthy subjects, from which it was concluded that VR is a promising treatment for anxiety disorders (Diemer et al., 2014). Another key area where social skills have been targeted using VR is autism: studies have also found that VR is a promising tool for improving social skills, cognition, and functioning (Kandalaft et al., 2013).

1.3 Using virtual reality to research, assess, and treat aspects of social functioning in psychosis

Psychosis is a growing area for VR assessment and treatment. Early VR studies (Ku et al., 2006; Ku et al., 2005) observed that patients with schizophrenia felt uncomfortable wearing HMDs. With the development of increasingly lightweight VR technology, other research groups have used HMDs with people with psychosis (Valmaggia et al., 2015). VR is emerging as a treatment option for psychosis (Freeman, 2008; Veling et al., 2014). Research participants with psychosis have found immersive VR acceptable and experienced few side effects (Fornells-Ambrojo et al., 2008; Freeman, 2008; Stinson et al., 2010). One review highlights that VR

applications for assessment and treatment of psychotic disorders appear to have a great potential for increasing our understanding of psychosis (Veling et al., 2014). Another review of VR in schizophrenia shows that VR is safe to use in this area and promises to add to existing treatments (Macedo et al., 2015). VR has been shown to allow the assessment of beliefs about the social environment in people with psychosis (Fornells-Ambrojo et al., 2008; Freeman, 2008). Immersive VR social scenarios have been shown to be acceptable and sufficiently realistic for people with psychosis (Veling et al., 2015), while social skills-based interventions that have figured prominently include emotion recognition (Souto et al., 2013), eye gaze (Choi et al., 2010; Han et al., 2014), interpersonal distance (Kim, Ku, et al., 2009), assertiveness (Park et al., 2011), and social cognition (Rus-Calafell et al., 2014).

1.4 Immersive and non-immersive virtual reality

Existing VR research highlights ambiguity in the term 'virtual reality' because it has been used to describe a wide array of interactive computer technologies and interventions, some involving interaction with a 2D computer screen, while others use an immersive, 3D head mounted display (HMD). Immersive VR technologies that use a HMD are becoming more widely available and the hardware lighter and more comfortable. Immersive VR is deemed more ecologically valid (Seidel & Chatelier, 2013) and has been described as 'combining computers, head-mounted displays (HMDs), body tracking sensors, specialized interface devices, and real time graphics to immerse a participant in a computer-generated simulated world that changes in a natural way with the head and body motion' (Rizzo et al., 2013). However, it has been argued that if the degree of immersion within a synthetic reality is relative to tasks to be performed or the skills developed, rather than relative to the level of perceptual experience, then a wider variety of environments could be called 'virtual' (Seidel & Chatelier, 2013). One example of a broader definition is multi-user domains (MUDS), internet-based virtual environments which do not require a HMD (Kamarainen et al., 2015) and have generally fallen under a broad definition of VR. Such broader definitions highlight the interactivity of the medium and the presence of the VR user (Steuer, 1992). While 2D interactivity in non-immersive VR may facilitate presence, it undoubtedly constitutes a qualitatively different experience of perceived reality to immersive VR. Immersive VR, by contrast, is likely to facilitate greater immersion and ecological validity given that it is 'a medium in which people respond with their whole bodies, treating what they perceive as real' (Slater, 2009). Future advances in VR technologies, including the developments of augmented reality (Barfield, 2015), mean that the definition of VR is in flux. Nevertheless, a convention in the current VR literature is to regard both immersive and non-immersive-VR as falling under a general category of VR, while adhering to an immersive/non-immersive distinction.

1.5 Aims

There is no previous systematic review of VR assessment and treatments that is specific to social functioning in psychosis. The evidence to date suggests that VR offers an effective assessment and treatment method for social functioning impairments in psychosis. The present review aims to synthesise the available research exploring the use of VR to assess and treat social functioning in psychosis, to determine whether VR assessment and treatment improve social functioning in people with psychosis. This review takes the pragmatic stance of including studies that authors describe as VR, where interactivity and presence are indicated; and given the differences in media, adheres to the widely used distinction between immersive VR technologies that use a HMD and non-immersive VR that uses a 2D computer screen.

2. METHODS

2.1 Selection procedure

A systematic review was conducted of VR studies that tested the assessment or treatment of social functioning for people with psychosis. Studies were included in the review if they were (a) peer-reviewed publications; (b) experimental; (c) written in the English language; (d) N>5; (e) used VR (either immersive or non-immersive); and (f) assessed or treated social functioning impairments in people with psychosis. People at ultra-high risk (UHR) of psychosis were included as UHR is associated with a very high risk of developing psychosis within the first three years of clinical presentation (Fusar-Poli et al., 2012).

2.2 Search criteria

Search terms were agreed by researchers (SR, LV, PG). Truncations and wild cards were used to identify mutations of terms. Studies for review were identified following a keyword search for the terms “virtual real*” OR “VR” OR “virtual enviro*” OR “virtual character*” OR “VCs” OR “avatar*” AND “social function*” OR “social dysfunction*” OR “social skill*” OR “social avoid*” OR “social cognit*” OR “social adapt*” OR “social behav*” OR “social inter*” OR “social stress*” OR “social learn*” OR “social percept*” OR “interpersonal” OR “inter-personal” AND “psycho*” OR “schiz*” OR “bipol*” OR “at risk mental state” OR “high risk” OR “early intervention” OR “paranoi*” OR “delus*” OR “halluci*”.

2.3 Procedure

The OvidSP platform was used to search PsycINFO, MEDLINE (Pubmed), and Embase. Additional searches were conducted using Web of Science, Cochrane Library, ProQuest, and Scopus. All database searches searched keyword, title, and abstract information for studies in English. For applicable databases (e.g. PsycINFO), key subject headings were exploded on OvidSP to identify studies that may not have been captured by the initial search strategy. See

Appendix I for the search strategy on OvidSP and Web of Science. Reference lists of key papers were screened to identify studies that may not have been captured by the initial search strategy. CRD guidance for systematic reviews was followed throughout. Reference management software Endnote was used to screen records. Unpublished dissertations, conference proceedings and abstracts without locatable full texts were excluded. A PRISMA flow chart was used to record studies that were excluded at each stage.

2.4 Quality assessment

The Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies method and tool was developed for use in public health. This tool was used to assess the quality of studies. EPHPP assesses six methodological dimensions: selection bias; study design; confounders; blinding; data collection methods; withdrawals and dropouts. A global rating for the paper is described as follows: Strong=no weak ratings; Moderate=one weak rating; Weak=two or more weak ratings on the subscales (the EPHPP is available online hpp.ca/tools.html). The EPHPP has good content and construct validity, and good inter-rater reliability (Thomas et al., 2004). One feature of the EPHPP scoring is that a study can score 'strong' overall even if it scores 'moderate' on all subscales.

3. RESULTS

3.1 Information extraction

Studies were identified on 30 January 2016. Database searching identified 2212 titles. Titles were reviewed manually. After removing duplicates and manuscripts not available in English, a total of 105 potential studies were identified for screening. Two further studies were identified by searching reference lists of key papers. After screening, 32 studies were included in the review. 12 studies were immersive VR and 20 studies were non-immersive VR. See Fig. 1.

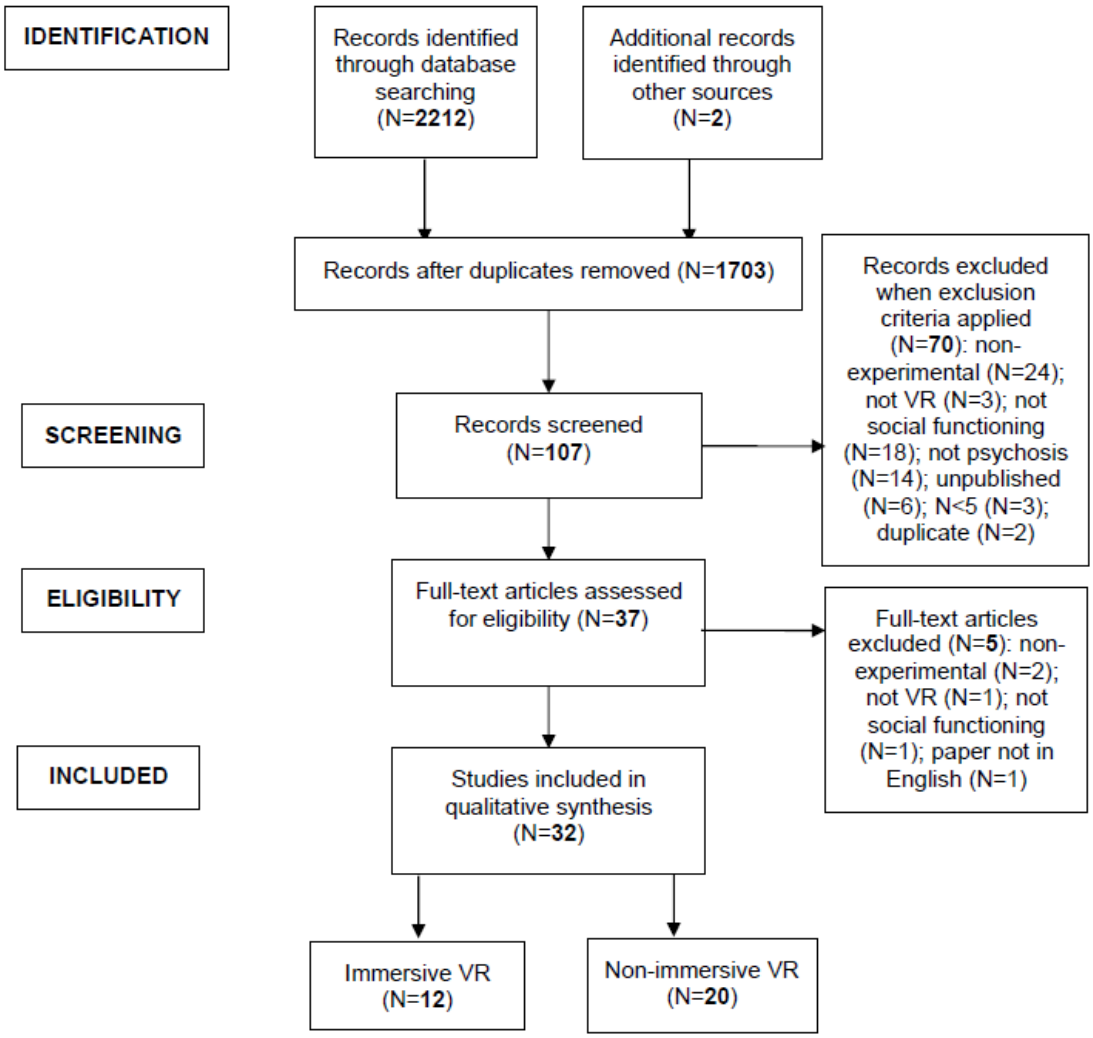

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram of selected studies

See Appendix II for screening results by individual database. At full-text review, five studies were excluded due to not satisfying the exclusion criteria: Chan et al. (2010) (Hong Kong, non-immersive VR, N=27 older adults with schizophrenia) was excluded for not testing social functioning impairments; Cho et al. (2007) (Korea, N=10 patients with schizophrenia) was excluded because the text was not in the English language; Delevoye-Turrell et al. (2011) (France) was excluded for not using VR; and Peyroux and Franck (2014) (France) and (Timmermans & Schilbach, 2014) (Scotland & Germany) were excluded for being non-experimental.

3.2 Study characteristics

The review identified 32 studies published between 2005 and 2015. Thirteen (41%) of the studies occurred in 2014 or 2015. Overall, seventeen (53%) studies were from Asia (Fifteen Korea, one China, and one Hong Kong); ten (31%) studies were from Europe (three Spain, two United Kingdom, two France, one Germany, one Portugal, and one Netherlands); and five (16%) studies were from USA.

3.3 Quality assessment

Quality assessment was completed by three independent reviewers (SR, LV, MR-C). Disagreements were resolved through discussion. 24 (75%) studies received an EPHPP global rating of strong; seven (22%) were rated as moderate, and one (3%) was rated as weak. See Tables 1 and 2 for study characteristics and breakdown of quality assessment for both immersive and non-immersive VR studies.

Table 1. Immersive VR study characteristics

Study	Country	SF domain	Assess (A)/ treat (T)	Clinical sample (control group – Y/N)	Participants	Mean age (SD)	VR apparatus	VR task	Measures	No. of Sessions (follow up – Y/N)	Main findings	EPHPP Global Rating
Choi et al. (2010)	Korea	Eye gaze	A	Inpatients with SZ (Y)	N=52: 26 patients (11M; 15F); 26 healthy controls (11M; 15F)	Patients 29.9 (7.9); controls 30.1 (6.9)	HMD; position tracker; computer; participants recorded on camcorder	Conversations with family, friends, and co-workers with positive and negative emotional contents	RAS; SES; PANAS; PQ, Co-PQ; VRQ	1 (N)	Less eye contact in patients	Strong
Han et al. (2014)	Korea	Eye gaze	A	Outpatients with SZ (Y)	N=45: 23 patients (10M, 13F); 22 healthy controls (9M, 19F).	Patients 28.9 (3.4); controls 27.0 (3.6).	HMD; position tracker; eye tracker attached to HMD	Multiparty conversation with 2 avatars	VREQ; PANSS, RPM; TMTB; PQ	1 (N)	Less eye contact in patients	Strong
Kim, Ku, et al. (2009)	Korea	Interpersonal distance; eye gaze	A	Inpatients with BD (Y)	N=40: 20 patients (10M, 10F); 20 healthy controls (10M, 10F)	Patients 30.1 (5.9); controls 27.7 (4.4)	HMD; position tracker; ear phones;	Interactions with 6 avatars varied across emotional types and gender	STAI; YMRS; HAMD	1 (N)	Greater interpersonal distance & less eye contact in patients.	Strong
Park et al. (2011)	Korea	Conversation skills; assertiveness; emotion expression; motivation	T	Inpatients with SZ (Y)	N=64: 64 patients – 33 in VR group (16M, 17F), 31 in non-VR group (18M, 13F); no healthy controls	Patients in VR group 28.1 (7.7); patients in non-VR group 31.2 (7.7)	HMD	Social skills training (10 role-plays).	RAS; RCS; SPSI-R	10 in 5 weeks (N)	Both interventions were useful for verbal social skills improvement with superiority of the traditional intervention in nonverbal skills	Strong
Park, Ku, Park, et al. (2009)	Korea	Conversation skills	T	Inpatients with paranoid SZ (Y)	N=33: 18 patients (all F) – 10 in Aripiprazole group, 8 in Risperidone group; 15 healthy controls (all F)	Patients in Aripiprazole group 30.2 (7.7); Patients in Risperidone group 29.3 (6.8); controls 28.1 (8.0)	HMD; receiver; transmitter	Conversations with avatars (self-introduction with stranger; making an appointment; with a co-worker).	SBS; RCS; PANSS; PANAS; BARS; SARS	6 (N)	Significant difference in functional skills between the patients and controls. Larger treatment effect than previous studies, and significant treatment x skills phase x group interaction effect	Strong
Park, Ku, Kim, et al. (2009)	Korea	Interpersonal distance & eye gaze	A	Inpatients with SZ (Y)	N=60: 30 patients (16M, 14F); 30 healthy controls (16M, 14F)	Patients 28.7 (5.5); controls 26.3 (4.3)	HMD; receiver; transmitter	Participants introduced themselves to an avatar.	PANSS, RPM	1 (N)	Patients had longer distances and gaze larger angles than controls.	Strong
Rus-Calafell et al. (2013)	Spain	Social cognition	T	Outpatients with SZ or SAD (N)	N=12: 12 patients (no gender information given)	Patients 36.5 (6.08)	Laptop with stereoscopic view; 3D glasses; headphones	Social skills training intervention	SCIP; CPT II; SUS	16 in 8 weeks (N)	High sense of presence in patients. Good verisimilitude and high acceptance of VR.	Moderate

Rus-Calafell et al. (2014)	Spain	Social cognition; social competence	T	Outpatients with SZ or SAD (N)	N=12: 12 patients (7M, 5F)	Patients 36.5 (6.01)	Laptop with stereoscopic view; 3D glasses; headphones	Social interactions with avatars, encouraging progressive learning of social skills	AI; PANSS, SSIT, SADS, SFS	16 (Y: 4 months)	Negative symptoms reduction; social skills improvements. Maintained at follow up	Strong
Souto et al. (2013)	Portugal	Emotion recognition	A	Inpatients with SZ (Y)	N=24: 12 patients (9M, 3F); 12 healthy controls (9M, 3F)	Patients 36.25 (5.754); controls 36.25 (5.754)	3D stereoscopic projection. with polarized glasses, and surround sound system; electroencephalogram	Facial stimuli emotion recognition task	MMSE; PSPS; GAFS; emotion recognition	1 (N)	Group difference was not statistically significant. Performance of people with schizophrenia was inferior	Strong
Valmaggia et al. (2015)	UK	Paranoia; social defeat	A	Outpatients with UHR mental state for psychosis (Y)	N=107: 64 patients (38M, 26F); 43 healthy controls (20M, 23F)	Patients 22.55 (4.01); controls 24.02 (4.01)	HMD	Tube train ride with avatar passengers	CAARMS; DASS; PrQ; SEDS; SCS; SDCS, SSPS	1 (N)	UHR participants reported higher social defeat and their paranoid appraisals were predicted by baseline social defeat	Strong
Valmaggia et al. (2007)	UK	Paranoia	A	Outpatients with UHR mental state for psychosis (N)	N=21: 21 patients (13M, 8F); no healthy controls	Patients 25.0 (4.7)	LCD shutter glasses with stereo view	Tube train ride with avatar passengers	Beads task; DASS; GPTS; ISPM; LHHS; NART; Post VR semi-structured Interview; PS; VAS; VRQ; WCST	1 (Y: 1 week)	VR did not increase anxiety or cause negative experiences	Strong
Veling et al. (2015)*	Netherlands	Paranoia	A	Patients with FEP: no in/outpatients information (Y)	N=41: 17 patients (14M, 3F); 24 healthy controls (20M, 4F)	Patients 27.3 (5.5); controls 29.0 (9.2)	Emagin Z800 3D Visor	Four virtual experiments during which participants in a virtual cafe´ look for avatars with digits on their clothing.	DACOBS; Galvanic skin response; GPTS; heart rate; IPQ; SERS; SIAS; SSPS, SSQ; VAS	1 (N)	Patients reported more paranoid thoughts, showed more proximity to the avatars and higher galvanic skin response to avatars of a different ethnicity from their own	Strong

Table 2. Non-immersive VR study characteristics

Study	Country	SF domain	Assess (A)/ treat (T)	Clinical sample (control group – Y/N)	Participants	Mean age (SD)	VR apparatus	VR task	Measures	No. of Sessions (follow up – Y/N)	Main findings	EPHPP global rating
Bell and Weinstein (2011)*	USA	Job interview skills	T	Patients with SZ or SAD – 1 with chronic PTSD; 1 with BPD (N)	N=10: 10 patients (5M, 5F)	Patients 42.3 (10.0)	2D screen	Job interview simulation and training program	VAS	1 (N)	Patients had a positive response to the simulation	Moderate
Dyck et al. (2010)	Germany	Emotion recognition	A	Out/inpatients with SZ (Y)	N=40: 20 patients (9F, 11M; two inpatients, 18 outpatients); 20 healthy controls (9F, 11M).	Patients 36.75 (1.99); controls 36.9 (2.23)	2D screen	Facial stimuli emotion recognition task	PANAS, PANSS; SCID	1 (N)	Emotion recognition impairments occurred with virtual characters	Strong
Gutierrez-Maldonado et al. (2012)	Spain	Emotion recognition	A	Outpatients with SZ or SAD (N)	N=30: 30 patients (no gender information given)	No information given	2D screen	Facial stimuli emotion recognition	PANSS, TAS-20	1 (N)	Overall there were no differences between VR presentation and photographs. Participants made fewer errors on fear and anger in the VR condition.	Moderate
Humm et al. (2014)	USA	Job interview skills	T	Outpatients with SZ and other SMI (Y)	N=96: 26 patients with ASD, 33 patients with PTSD, and 37 with SZ/other – 25 in VR group (64.0% M); 12 in non-VR group (16.7% M); no healthy controls.	Patients with SZ – in VR group 50.0 (11.6); in non-VR group 44.3 (10.3).	2D screen	Job interview simulation and training program	BLERT; RBANS	5 (N)	VR group participants scored higher in the role-play interviews and in self-assessment	Moderate
Kim et al. (2007)	Korea	Social cue perception, emotion recognition	A	Inpatients with SZ (Y)	N=60: 30 patients (16M, 14F); 30 healthy controls (16M, 14F)	Patients 29.63 (4.98); controls 29.50 (5.33)	Projector; 2D screen; joystick; external speakers	Social stimuli and emotion recognition task	PANSS, ITQ, Korean WAIS, PQ, VRQ	1 (N)	Patients were poorer on emotion recognition task	Strong
Kim et al. (2005)	Korea	Social cue perception; emotion recognition	A	Inpatients with SZ (Y)	N=34: 17 patients (12M, 5F); 17 healthy controls (12M, 5F)	Patients 30.41 (5.36); controls 30.05 (6.07)	Projector; 2D screen; joystick; external speakers	Social stimuli and emotion recognition task	PANSS, ITQ, Korean WAIS, PQ, VRQ	1 (N)	Patients were poorer on social cue perception task	Strong
Kim, Jung, et al. (2009)	Korea	Social cognition	A	Right-handed euthymic outpatients with BD (Y)	N=28: 14 patients (8M, 6F); 14 healthy controls (8M, 6F)	Patients 30.4 (5.9); controls 27.5 (3.3)	2D screen	Facial stimuli emotion recognition task	AHQ; HAMD; Korean WAIS; PQ; YMRS	1 (N)	Patients had delayed reaction times in emotional conditions and reduced activation in mirror neuron system.	Strong
Ku et al. (2007)	Korea	Conversation skills	T	Inpatients with SZ (N)	N=10: 10 patients (5M, 5F); no healthy controls	Patients 28.8 (9.07)	Large 2D screen; projector; joystick	Greet avatars; manage conversation; listen and speak; end conversation	PANSS; VAS	1 (N)	Patients found VR social skills task acceptable	Moderate

Ku et al. (2006); Ku et al. (2005)**	Korea	Interpersonal distance; verbal response time	A	Inpatients with SZ (N)	N=11: 11 patients (5M, 6F); no healthy controls	Patients 29.54 (8.95)	Personal computer; large 2D screen; projector; joystick	Initiate conversation with male avatar and answer questions	PANSS, VAS	1 (N)	Interpersonal distance negatively correlated with the negative syndrome scale (PANSS). Patients perceived avatar as real	Moderate
Oker et al. (2015)	France	Social cognition; emotion recognition	A	Patients with SZ – no information on in/outpatients (N)	N=29: 14 patients; 15 healthy controls (no gender information given)	No age information given	2D screen	Facial stimuli emotion recognition task during virtual card game	Idiosyncratic questionnaire	1 (N)	Patients found the task acceptable and their results were comparable with healthy controls	Weak
Park et al. (2014)	Korea	Emotional perception; social decision-making	A	Outpatients with SZ (Y)	N=57: 27 patients (13M, 14F); 30 controls (13M, 17F)	Patients 33.0 (3.7); 31.7 (2.1)	2D screen	VR task to build intimacy with virtual avatars and to estimate the level of intimacy that participants feel with four avatars	LSAS; PANSS; RSES; SPM	1 (N)	Intimacy scores for intimate avatars were not significantly different between groups, but those for distant avatars were significantly higher in patients than in controls.	Strong
Park, Kim, et al. (2009)	Korea	Emotion attribution style	A	Outpatients with SZ (Y)	N=31: 15 patients; 16 healthy controls (no gender information given)	No age information given	2D screen, fMRI	Attribution task of emotional or neutral behaviour of an avatar	PANSS	1 (N)	First study to report neural basis of attributional style in patients with schizophrenia. Results suggest patients have functional deficits in mirror neuron system when attributing positive behaviours, which may be related to a lack of inner simulation and empathy and negative symptoms	Strong
Shin et al. (2015)	Korea	Social perception	A	Outpatients with SZ (Y)	N=36: 17 patients (11M, 6F); 19 healthy controls (12M, 7F)	Patients 31.0 (6.1); controls 28.21 (4.2)	2D screen; fMRI	To determine if avatar's speech was appropriate in an avatar conversation	PANSS; SAS; SC–LFS	1 (N)	Dysfunction of the dorsolateral prefrontal cortex- superior temporal sulcus network may underlie patients' abnormal social perception in various social situations of daily life	Strong
Smith, Fleming, Wright, Roberts, et al. (2015)	USA	Job interview skills	T	Patients with SZ or SAD – no information on in/outpatients (Y)	N=32: 32 patients - 21 in VR group (54.5% M); 11 in non VR group (52.4% M); no healthy controls	Patients in VR group 40.8 (12.2); patients in non-VR group 39.1 (10.6)	2D screen	Job interview simulation and training program	BLERT; EPT; RBANS; VAS	10 (Y: 6 months)	VR was easy-to-use and helpful. VR group demonstrated increased role-play scores between pre-test and post-test while controls did not	Strong
Smith, Fleming, Wright, Jordan, et al. (2015)	USA	Job interview skills	A	Patients with a diagnosis of BD, MDD, SZ, or SAD & U.S. military veterans with PTSD & comorbid mood/ psychotic disorder – no information on in/outpatients (Y)	N=51: 51 patients - 39 in VR group (29M, 10F); 12 in non VR group (6M, 6F); no healthy controls	Patients in VR group 47.0 (12.4); patients in non-VR group 49.1 (10.9)	2D screen	Job interview simulation and training program	BLERT; RBANS	1 (N)	VR group were more likely to receive a job offer.	Strong

Smith, Ginger, Wright, Wright, Humm, et al. (2014)	USA	Job interview skills	T	Outpatients with MDD, BD, SZ or SAD (Y)	N=37: 37 patients - 25 in VR group (64.0% M); 12 in non VR group (16.7% M); no healthy control group	Patients in VR group 50.0 (11.6); patients in non-VR group 44.3 (10.3)	2D screen	Job interview simulation and training program	BLERT; EPT; RBANS; VAS	10 (N)	Participants found VR easy-to-use. VR group improved job interview role-play performance	Strong
Song et al. (2015)	China	Emotion recognition	A	Outpatients with SZ (Y)	N=85: 44 patients (20M, 24F); 41 healthy controls (17M, 24F)	Patients 35.5 (11.1); controls 32.4 (13.3)	2D computer screen.	Facial stimuli emotion recognition task	PANSS; VAS	1 (N)	Patients had greater difficulty than controls identifying facial emotions	Strong
Thirioux et al. (2014)	France	Empathic processing	A	In/outpatients with SZ (Y)	N=20: 10 patients (all M); 10 healthy controls (all M)	Patients 33.3 (6.4); controls 32.5 (5.8)	Large 2D screen	Participants interacted with a computer-generated female tightrope on the screen	PANSS	1 (N)	Severity of negative symptoms in schizophrenia related to disturbances of spontaneous (''online'') empathic processing in association with lower scoring self-reported trait cognitive empathy	Strong
Tsang and Man (2013)	Hong Kong	Vocational skills; cognitive function; self-efficacy	T	Inpatients with SZ (Y)	N=75: 75 patients - 25 in VR group (28% M); 25 in non-VR group 1 (60% M); 25 in non-VR group 2 (44% M); no healthy controls	Patients in VR group 39.60 (7.96); patients in non-VR group 1 40.76 (9.19), patients in non-VR group 2 41.56 (9.94)	2D screen	VR vocational training including greeting and directing customers	BNCE, DVT, RBMT, WCST, VCRT	10 (Y: 1 month)	VR group performed better in cognitive functioning, executive functions, problem solving, categorization, memory, attention and self-efficacy	Strong

* Study identified through other sources; ** Studies present the same data

KEY: *Demographics*: M=male; F=female; *Conditions*: SF=social functioning; SZ=schizophrenia; FEP=first episode psychosis; UHR=ultra-high risk; BD=bipolar disorder; SAD=schizoaffective disorder; MDD=major depressive disorder; PTSD= post-traumatic stress disorder; BPD=borderline personality disorder; SMI=serious mental illness; *Virtual Reality*: VR=virtual reality; HMD=head mounted display; *Measures:* AI: Assertion inventory; AHQ: Annett's handedness questionnaire; BARS: Barnes akathisia rating scale; BLERT: Bell-Lysaker emotion recognition task; BNCE: Brief neuropsychological cognitive examination; CAARMS: Comprehensive assessment of the at risk mental state; Co-PQ: Co-presence questionnaire; CPT II: Continuous performance test; DACOBS: Davos assessment of cognitive biases scale; DASS: Depression, Anxiety and Stress Scale; DVT: Digit vigilance test; EPHPP: Effective public heath practice project quality assessment tool; EPT: Emotional perspective-taking; GAF: Global assessment of functioning scale; GPTS: Green paranoid thoughts scale; HAMD: Hamilton depression rating scale; IPQ: Igroup presence questionnaire; IPSM: Interpersonal sensitivity scale; ITQ: Immersive tendency questionnaire; LSAS: Liebowitz social anxiety scale; LSHS: Launay-Slade hallucinations scale; MMSE: Mini mental state examination; NART: National adult reading test; PANAS: Positive and negative affect schedule; PANSS: Positive and negative symptoms scale; PQ: Presence questionnaire; PrQ: Prodromal questionnaire; PS: Paranoia scale; PSPS: Personal and social performance scale; RAS: Rathus assertiveness scale; RBANS: Repeatable battery for the assessment of neuropsychological status; RBMT: Rivermead behavioural memory test; RCS: Relationship change scale; RPM: Raven's progressive matrices; RSES: Rosenberg self-esteem scale; SADS: Social avoidance and distress scale; SARS: Simpson-Angus rating scale; SAS: Social anhedonia scale; SBS: Social behavior scale; SCID: Standard clinical interview for DSM disorders; SCIP: Screen for cognitive impairment in psychiatry; SC–LFS: Strauss–Carpenter level of functioning scale; SCS: Social comparison scale; SEDS: Social entrapment and defeat scales; SERS: Self-esteem rating scale; SES: Self-efficacy scale; SFS: Social functioning scale; SIAS: Social interaction anxiety scale; SPM: Standard progressive matrices; SPSI-R: Social problem solving inventory-revised; SSIT: Simulated social interaction test; SSPS: Social state and paranoia scale; SSQ: Simulator sickness questionnaire; STAI: Spielberger state-trait anxiety inventory; SUS: Sense of presence scale; TAS-20: Toronto Alexithymia Scale; TMTB: Trail making test b; VAS: Visual analogical scales; VCRT: Vocational cognitive rating scale; VRQ: Virtual reality questionnaire; VREQ: Virtual reality experience questionnaire; WAIS: Wechsler adult intelligence scale; WCST: Wisconsin card sorting test; YMRS: Young mania rating scale

3.4 Immersive virtual reality studies

There were twelve immersive VR studies published between 2007 and 2015. Eleven (92%) studies had an EPHPP global rating of strong and one (8%) was rated as moderate. In terms of the six methodological dimensions, six studies received a moderate rating for all dimensions; two studies received 1/6 strong ratings; and four studies received 2/6 strong ratings. See Appendix IV for a full breakdown of quality results.

Country of origin

Six studies were from Asia and six studies were from Europe. See Table 3 for breakdown of studies' country of origin.

Table 3. Country of origin of immersive VR studies

Country	N
Asia	
Korea	6
Europe	
Netherlands	1
Portugal	1
Spain	2
United Kingdom	2

Participant diagnoses

Studies have been mainly conducted with people with schizophrenia. See Table 4 for breakdown of participant diagnoses.

Table 4. Participant diagnoses for immersive VR studies

Diagnosis	N
Bipolar disorder	1
First episode psychosis	1
Schizophrenia	8
Ultra-high risk of psychosis	2

Treatment and assessment domains

There were eight assessment studies and four treatment studies. See Table 5 for breakdown of assessment and treatment domains.

Table 5. Assessment and treatment domains of immersive VR studies

Country	N
Assessment	
Eye gaze	4*
Interpersonal distance	2*
Social cognition/emotion recognition	1
Paranoid ideation	3
Treatment	
Conversation skills	2
Social cognition/emotion recognition	2

*Two studies assessed both eye gaze and interpersonal distance

Assessment

Assessment studies have sought to assess behavioural indicators of social functioning, such as eye gaze and interpersonal distance; and cognitive indicators of social functioning, such as social cognition and paranoid ideation. Studies have been cross-sectional and all studies reported positive results. The behavioural studies of eye gaze and interpersonal distance show that people with schizophrenia use less eye contact (Choi et al., 2010; Han et al., 2014) and greater interpersonal distance (Park, Ku, Kim, et al., 2009) in social situations with virtual humans when compared with healthy controls. A similar result has been replicated for people with bipolar disorder (Kim, Ku, et al., 2009). In terms of the cognitive research, one study has assessed emotion recognition and found inferior performance on a facial stimuli emotion recognition task in people with schizophrenia when compared with healthy controls (Souto et al., 2013). Studies of paranoid ideation and social defeat show that VR social situations are acceptable and do not in themselves cause negative outcomes (Valmaggia et al., 2007); that people at ultra-high risk of psychosis report greater paranoid ideation and social defeat (Valmaggia et al., 2015) when compared with healthy controls. A similar result for paranoid ideation was reported for people with first episode psychosis (Veling et al., 2015).

Treatment

Treatment studies have mainly been small pilots, two with control groups and two without, which have sought to develop social skills with behavioural and cognitive components for people with schizophrenia by targeting conversation skills (Park et al., 2011; Park, Ku, Park, et al., 2009) and social cognition (Rus-Calafell et al., 2014; Rus-Calafell et al., 2013). All studies reported positive results. Participants reported that VR social skills training had high acceptability and verisimilitude (Rus-Calafell et al., 2013) and the pilot of the intervention brought about reduction in negative symptoms and improvement in social skills (Rus-Calafell et al., 2014). Immersive VR conversation role-plays were shown to produce improvement in functional skills in people with schizophrenia. One study was a randomised controlled trial with a moderate sample size (Park et al., 2011); it found that VR roleplays were effective in developing verbal social skills. Sample sizes have otherwise been small.

3.5 Non-immersive virtual reality studies

There were twenty non-immersive VR studies published between 2005 and 2015. Two separately published studies (Ku et al., 2006; Ku et al., 2005) presented the same data. Thirteen (65%) studies had an EPHPP global rating of strong, six (30%) were rated as moderate, and one (5%) was rated as weak. In terms of the six methodological dimensions, two studies received 1/6 strong ratings; and three studies received 2/6 strong ratings, and one study received 3/6 strong ratings. All other studies received either all moderate ratings or a combination of moderate and weak. See Appendix IV for a full breakdown of quality results.

Country of origin

Eleven studies were from Asia; 5 studies were from North America; and 4 studies were from Europe. See Table 6 for breakdown of studies' country of origin.

Table 6. Country of origin of non-immersive VR studies

Country	N
Asia	
China	1
Hong Kong	1
Korea	9
Europe	
France	2
Germany	1
Spain	1
North America	
Unites States of America	5

Participant diagnoses

Studies have been mainly conducted with people with schizophrenia, or with schizophrenia and other diagnoses. See Table 7 for breakdown of participant diagnoses.

Table 7. Participant diagnoses for non-immersive VR studies

Diagnosis	N
Bipolar disorder	1
Schizophrenia	13
Schizophrenia and other serious mental illnesses	6

Treatment and assessment domains

There were 14 assessment studies and 6 treatment studies. See Table 8 for breakdown of assessment and treatment domains.

Table 8. Assessment and treatment domains of non-immersive VR studies

Country	N
Assessment	
Empathic processing	1
Interpersonal distance	2
Social cognition/emotion recognition	9
Social perception	1
Vocational skills	1
Treatment	
Conversation skills	1
Job interview skills	5

Assessment

Assessment studies have mainly assessed cognitive indicators of social functioning, with a particular focus on social cognition. Studies have been cross-sectional and all studies reported poorer performance in people with psychosis. Studies show that people with schizophrenia have found VR emotion recognition task acceptable (Oker et al., 2015); they are poorer at emotion recognition (Kim et al., 2007); and show delayed reaction times and reduced activation in the mirror neuron system (Kim, Jung, et al., 2009).

Treatment

Treatment interventions have largely focused on job interview training and simulations. These have mainly been pilot studies with small sample sizes. Interventions are shown to be acceptable (Bell & Weinstein, 2011; Ku et al., 2007); extended treatments that use 5-10 sessions of job interview training have shown improved job interview performance compared with service users who did not receive the intervention (Smith, Ginger, Wright, Wright, Bell, et al., 2014). Results have been sustained at follow up (Smith, Fleming, Roberts, et al., 2015; Tsang & Man, 2013).

4. DISCUSSION

4.1 Main findings

This review of the literature on VR assessment and treatments for social function in psychosis shows that VR has potential. Studies show positive findings but evidence is limited. A large majority of studies received an EPHPP global rating of strong but analysis of individual methodological domains on the EPHPP reveals that studies have methodological weaknesses, which will be discussed below. Key social functioning domains in assessment studies tend to divide into those that target cognitive abilities, such as social cognition or emotion recognition; or those that target behavioural indicators, such as eye gaze and interpersonal distance. Treatment packages have been shown to be effective but they have been fewer in number and focused on general social skills or job interview/vocational skills. VR studies in this area have

predominantly included people with schizophrenia as participants, with very few studies on bipolar disorder, first episode psychosis, or ultra-high risk. The majority of the studies have been conducted in Asia, specifically in Korea, with fewer in Europe and the USA.

4.2 Assessment

This review indicates that VR can be used to measure impairments in emotion recognition, processing, or general social cognition. Theory of mind deficits can be a marker of psychosis. People with psychosis have been shown to have severe and persistent problems with emotion recognition (Daros et al., 2014). This deficit is present early and tends to be present for the course of the illness (Comparelli et al., 2013). Social cognitive impairments interfere with social connections and have been shown to be strong determinants of the degree of impaired daily functioning in people with schizophrenia (Green et al., 2015). Emotion recognition impairments have been shown to be different across psychotic disorders (Ruocco et al., 2014) so it may be important to consider this in the future development of such VR tests. VR studies show that eye gaze and interpersonal distance are a key avoidance behaviour of socially anxious people within a highly controlled situation (Wieser et al., 2010). In psychosis, the behavioural studies showing reduced eye gaze and increased interpersonal distance have been replicated in four immersive studies, all with N>40 (Choi et al., 2010; Han et al., 2014; Kim, Ku, et al., 2009; Park, Ku, Park, et al., 2009). However, identifying such inferior performance does not constitute a novel finding: eye gaze and interpersonal distance in psychosis have been studied using non-VR tasks, sometimes with results that conflict with the VR findings (Hooker & Park, 2005; Nechamkin et al., 2003; Ponizovsky et al., 2013). Using eye and positioning tracking technology in conjunction with a controlled immersive VR environment might appear to be an optimal way of measuring eye gaze or interpersonal distance. However, a general problem in this field is that VR tasks have not been validated in comparison with other methods. Future studies need to determine if VR is as effective and ecologically valid as non-VR tasks and what the limitations of VR might be.

4.3 Treatment

Supporting social relationships and employment opportunities has been shown to be instrumental to recovery (Gayer-Anderson & Morgan, 2013; Shanks et al., 2013; Tew et al., 2011) and improving wellbeing (Schrank et al., 2014; Slade, 2012) for people with psychosis. The ten VR treatment studies (four immersive VR; six non-immersive VR) have mainly used a multi-session intervention. They have been mostly pilots, not randomised, and sometimes without a control condition. Studies provide some initial evidence that VR tasks can improve social skills in people with psychosis. One VR social skills package was shown to effectively improve negative symptoms, social anxiety and pro-social activities although it did not use a

control condition (Rus-Calafell et al., 2014). In another VR social skills training package, improvements were observed only in conversational skills but not in vocal and nonverbal skills (Park et al., 2011). VR studies have led to tangible outcomes such as higher success at job interviews compared with a control group (Smith, Fleming, Wright, Roberts, et al., 2015). The area of job interview training has figured prominently in the VR treatment literature. Other studies have shown that VR job interview simulations are acceptable for people with psychosis (Bell & Weinstein, 2011) and they do better in real-world interview roleplays after VR training (Humm et al., 2014). In addition, an important finding is that these positive gains in social skills have been maintained at follow-up (Rus-Calafell et al., 2014; Smith, Fleming, Wright, Jordan, et al., 2015). However, it is acknowledged that sample sizes have been small and interventions relatively short (Park, Ku, Park, et al., 2009). Several social skills simulations have been acceptability and feasibility pilots and only used one session (Bell & Weinstein, 2011; Ku et al., 2007). In general, the evidence suggests that the ecological validity of VR has the potential to provide therapist-assisted treatment conditions but studies are limited in scope.

4.4 Immersive and non-immersive virtual reality

Immersive VR that uses a lighter HMD is now a more widely available and economically viable option that appears to be acceptable to people with psychosis; thus dispelling earlier concerns that the HMD would be too heavy and uncomfortable (Ku et al., 2006; Ku et al., 2005). It has been argued that immersive VR offers a fundamentally different intervention to non-immersive VR by enabling participants greater verisimilitude (Rus-Calafell et al., 2013) and egocentric encoding of a scene they are immersed in, rather than allocentric encoding on a computer screen (Kozhevnikov et al., 2013). Similarly researchers have argued that immersive VR can support effective co-presence in constrained situations (Steed & Schroeder, 2015); while it allows a direct feeling of objects and events that are physically out of reach; and supports training in safe environments that avoid potential real dangers (Freina & Ott, 2015). The evolution of immersive VR technology appears to offer greater ecological validity and reduces potentially intrusive by-products of social interventions, such as the ‘uncanny valley’ (Ho, 2015). The added ecological validity of immersive VR appears to offer a promising option for VR interventions targeting social functioning, compared with non-immersive VR, although comparisons have generally been between VR and non-VR.

One advantage of immersive VR with a HMD and head tracking technology may be to allow researchers to investigate behavioural indicators of social functioning that have previously been harder to measure. One example is eye gaze and interpersonal distance (Kim, Ku, et al., 2009; Park, Ku, Kim, et al., 2009) although there have been limitations in this area.

4.5 Limitations

This is a relatively small area of research with few studies; many studies are pilots with small sample sizes, few have control groups and there are very few RCTs. There is only one immersive VR RCT (Park et al., 2011) and only 6 non-immersive VR RCTs. The validity of the assessment tools used in VR not yet been fully established and there is a lack of replication, especially in treatment studies. Since most studies create new environments there is a real challenge to establish validity and reliability. Some studies fail to report important participant demographic information, such as age (Gutierrez-Maldonado et al., 2012; Oker et al., 2015; Park, Ku, Park, et al., 2009), experience of cybersickness, which has proven to be a difficult concept to measure (Davis et al., 2014); and provide little information about apparatus (Humm et al., 2014). Many treatment studies have not included a follow up (Park et al., 2011; Rus-Calafell et al., 2013), which would give greater credence to the findings.

Many studies have limitations in that they do not produce novel findings but they do replicate results established with non-VR tasks. This suggests that VR might have similar benefits in comparison to real life social situation tasks to assess social functioning. For instance, an advantage of VR facial stimuli emotion recognition tasks might be to provide a controlled environment against which to test impairments, such as social cognition or emotion recognition deficits. VR has the advantage of being conducted in a lab, can be manipulated, controlled, tailored, and is potentially more cost-effective.

VR studies on social functioning impairments in psychosis have only twice used people with bipolar disorder (Kim, Jung, et al., 2009; Kim, Ku, et al., 2009) so this remains an under-researched area. Equally, some studies include a mixed sample of participants with psychosis or other serious mental illnesses, which makes it difficult to draw diagnosis-specific conclusions. Studies have been conducted worldwide so cross-cultural factors must also be considered when comparing studies.

In part due to technological limitations, studies have been fairly narrow in scope. Assessment research has tended to focus on discrete indicators of social functioning, such as eye gaze or interpersonal distance. From this research, there is evidence that VR can be used as an effective research tool, but it unclear whether general conclusions about social functioning can always be drawn. The concept of social functioning includes components focused on work, social activities, and relationships with partners and family. Similarly, treatment research has tended towards a narrow focus on job interview or vocational skills, or general social skills with new people (represented by avatars). While this research shows promising results, albeit mostly in small and uncontrolled studies, it remains to be seen how the ecological validity and evolving

technology of VR can be harnessed to expand to more sophisticated interventions that target family, friendships, and romantic relationships, as well as how VR technology can be harnessed to accommodate the reciprocal nature of social interactions.

Limitations of the EPHPP quality assessment tool should be acknowledged. For instance, studies have shown that EPHPP and Cochrane Collaboration Risk of Bias Tool perform differently when evaluating the risk of bias or methodological quality of studies (Armijo-Olivo et al., 2012). In the present review, the methodology for generating overall ratings has resulted in a high number of strong studies, especially when compared to the proportionately low number of strong methodological dimensions of the same studies and to the fact that the analysis of study characteristics shows that the majority of studies are pilots with relatively small sample sizes. Consequently, the individual methodological dimensions may represent a better way of evaluating the studies and has been taken into account in the present review.

4.6 Future research

Future VR research on social functioning in psychosis might seek to develop more comprehensive, standardised, methods of assessment, which attempts to establish their validity and reliability, and similarly for evidence-based treatments; and to broaden the demographic of participants and the range of social functioning indicators. Central to this aim will be the development of more interactive, multi-avatar social situation tasks, in which real-time therapeutic treatments for social functioning impairments can be tested and carried out, and correlates and key mechanisms identified.

As technology evolves, it will be important for researchers to broaden the focus of social functioning to include dynamics within existing personal relationships. Technological limitations currently impede this process, although non-immersive VR studies have already shown that people with psychosis can create an avatar of an entity known to them (Leff et al., 2014; Leff et al., 2013). Outside of psychosis research, the range of VR social functioning studies is broader, including areas such as VR dating (Frost et al., 2008). The next stage in VR mental health research may be the development of technology that allows clinicians to work with participants to co-create more sophisticated avatars in immersive VR. Virtual worlds may increasingly be harnessed by immersive VR for social interventions (Bainbridge, 2007). Communication and social networking is expected to be transformed in the age of virtual reality (Blascovich & Bailenson, 2011). Future technologies may seek to further blend what is ‘real’ and what is ‘virtual’ in ways already being seen with the development of augmented reality and gamification (Kapp, 2012).

4.7 Clinical recommendations

Evidence is limited but VR tasks can be used to measure impairments in emotion recognition, processing, or general social cognition, and can improve social skills in people with psychosis. The ecological validity of VR has the potential to provide therapist-assisted treatment conditions. Levels of immersion and cybersickness are important factors for clinicians to consider when administering VR tasks.

4.8 Conclusion

Evidence suggests that VR can be used to improve the assessment and treatment of aspects of social functioning in people with psychosis but, given study limitations and the lack of follow up results, more research is needed to be able to draw robust conclusions.

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Appendix I Search strategy

OvidSP Search Strategy

1	virtual real*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2	vr.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3	virtual enviro*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
4	virtual character*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
5	VCs.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
6	avatar*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
7	1 or 2 or 3 or 4 or 5 or 6
8	social function*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
9	social dysfunction*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
10	social skill*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
11	social avoid*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
12	social adapt*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
13	social behav*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
14	social inter*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
15	social stress*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
16	social learn*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
17	social percept*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
18	interpersonal.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
19	inter-personal.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
20	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	7 and 20
22	exp Virtual Reality/
23	7 or 22
24	exp social behavior/

25	20 or 24
26	23 and 25
27	limit 26 to english language

Web of Science Search Strategy

Web of Science Core Collection 1900-2016

# 23 **763**	#21 AND #20 Refined by: LANGUAGES: (ENGLISH) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years		Select to combine sets.	Select to delete this set.
# 22 **776**	#21 AND #20 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 21 **133,082**	#19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 20 **42,759**	#6 OR #5 OR #4 OR #3 OR #2 OR #1 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 19 **677**	**TOPIC:** (inter-personal) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 18 **45,522**	**TOPIC:** (interpersonal) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 17 **2,963**	**TOPIC:** (“social percept*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 16 **5,747**	**TOPIC:** (“social learn*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 15 **4,561**	**TOPIC:** (“social stress*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 14 **28,785**	**TOPIC:** (“social inter*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 13 **20,037**	**TOPIC:** (“social behav*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine sets.	Select to delete this set.
# 12 **1,122**	**TOPIC:** (“social adapt*”) Indexes=SCI-EXPANDED, SSCI, A&HCI,	Edit	Select to combine sets.	Select to delete this set.

		CPCI-S, CPCI-SSH, ESCI Timespan=All years			
# 11	**15,479**	**TOPIC:** (“social cognit*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 10	**511**	**TOPIC:** (“social avoid*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 9	**7,321**	**TOPIC:** (“social skill*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 8	**777**	**TOPIC:** (“social dysfunction*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 7	**11,344**	**TOPIC:** (“social function*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 6	**3,445**	TS=(“avatar*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 5	**1,674**	**TOPIC:** (VCs) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 4	**837**	**TOPIC:** (“virtual character*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 3	**13,877**	**TOPIC:** (“virtual enviro*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 2	**11,486**	**TOPIC:** (VR) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.
# 1	**20,866**	**TOPIC:** (“virtual real*”) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years	Edit	Select to combine	Select to sets. delete this set.

Appendix II Search results by database

Table 9. Database search results

Database	Results
PsycINFO 1806 to January Week 4 2016	329
MEDLINE(R) 1946 to January Week 3 2016	135
Embase 1974 to 2016 Week 05	648
PsycARTICLES	370
Web of Science Core Collection 1900 to 2016	205
Cochrane Library	18
Scopus	485
ProQuest Social Sciences Premium Collection (Subject Headings): Scholarly Journals	22
Total	2212
Total after deduplication function used in Endnote	1701
Total after title search	105

Appendix III Quality assessment tool

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and** the study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or** blinding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 - 100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 - 100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1	**STRONG**
2	**MODERATE**
3	**WEAK**

Appendix IV Full quality assessment results

Table 10. Immersive VR studies quality assessment

Study	A. Selection bias	B. Study design	C. Confounders	D. Blinding	E. Data collection method	F. Withdrawals and drop out	Overall rating
Choi et al, 2010	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) No. No difference in gender, age, education and IQ. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Han et al, 2014	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) No. No difference in age and education. There was a difference in reasoning ability and attention. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Kim, Ku at al, 2009	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) No difference in gender, age, education, IQ, state anxiety, trait anxiety, (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Park et al, 2011	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation not described, therefore CCT =STRONG	(Q1) No. No difference in gender, age, marital status, previous social skills treatments, medications, age at illness onset, education, previous psychiatric admissions, baseline scores on outcome measures (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 2. 60-79% (63/91=69%) =MODERATE	1. STRONG
Park, Ku, Park et al, 2009	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) No. No difference in gender, age, age at illness onset, education, baseline scores on outcome measures (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't ell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 2. 80-100% (33/39=85%) =STRONG	1. STRONG
Park, Ku, Kim et al, 2009	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) Yes. No differences in gender, employment, and marital status. Differences in education and intellectual function. (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 2. No. (Q2) 5. Not applicable (Retrospective case control) =MODERATE	1. STRONG
Rus-Calafell et al, 2013	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort =MODERATE	(Q1) 3. Can't tell (Q2) 4. Can't tell =WEAK	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	2. MODERATE

Rus-Calafell et al, 2014	(Q1) 3. Somewhat likely (Q2) 2. 60-79% agreement (15/20=75%) =MODERATE	5. Cohort =MODERATE	(Q1) 1. Yes (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 1. Yes =STRONG	(Q1) 1. Yes (Q2) 1. 80-100% (12/15=80%) =STRONG	1. STRONG
Souto et al, 2013	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) Yes. No difference in age and gender. Difference in Marital status, education, and employment. (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Valmaggia et al, 2015	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) Yes. No difference in age, gender, ethnicity. There was a difference in employment, education, reading ability. These confounders were controlled for in analysis. (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 1. Yes =STRONG	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Valmaggia et al, 2007	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort =MODERATE	(Q1) 1. Yes (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 1. Yes =STRONG	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Veling et al, 2014	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG

Table 11. Non-immersive VR studies quality assessment

Study	A. Selection bias	B. Study design	C. Confounders	D. Blinding	E. Data collection method	F. Withdrawals and drop out	Overall rating
Dyck et al. (2010)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 2. No. No difference in age, gender, education, and parental education. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Gutierrez-Maldonado et al. (2012)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort =MODERATE	(Q1) 3. Can't tell (Q2) 4. Can't tell =WEAK	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	2. MODERATE
Humm et al. (2014)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation not described, therefore CCT =STRONG	(Q1) 3. Can't tell (Q2) 4. Can't tell =WEAK	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 1. 80-100% (59/63=94%) =STRONG	2. MODERATE
Kim, Jung, et al. (2009)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 2. No. No difference in age, gender, education, and IQ. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Kim et al. (2005)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 2. No. No difference in age, gender, and computer-using experience. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Kim et al. (2007)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 2. No. No difference in age, gender, and computer-using experience. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Ku et al. (2007)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort =MODERATE	(Q1) 1. Yes. No difference in gender. Other potential confounders not mentioned (Q2) 3. Less than 60% (few or none) =WEAK	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e.	2. MODERATE

						retrospective case-control) =MODERATE	
Ku et al. (2006); Ku et al. (2005)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort =MODERATE	(Q1) 1. Yes. No difference in gender. Other potential confounders not mentioned (Q2) 3. Less than 60% (few or none) =WEAK	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	2. MODERATE
Oker et al. (2015)	(Q1) 4. Can't tell (Q2) 5. Can't tell =WEAK	4. Case control Not randomised =MODERATE	(Q1) 3. Can't tell (Q2) 4. Can't tell =WEAK	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =WEAK	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	3. WEAK
Park, Kim et al, 2009	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes. No difference in age, gender, and education duration. There was a difference in IQ. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Park et al. (2014)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes. No difference in age, gender, and social anxiety. There was a difference in education and self-esteem. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Shin et al. (2015)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes. No difference in age, gender, and education. There was a difference in IQ and social anhedonia. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Smith, Fleming, Wright, Jordan, et al. (2015)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation not described, therefore CCT =STRONG	(Q1) No. No difference in demographic characteristics and clinical, cognitive, and vocational histories. (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Smith, Fleming, Wright, Roberts, et al. (2015)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation not described, therefore CCT =STRONG	(Q1) No. No difference in demographic characteristics and clinical, cognitive, and vocational histories. (Q2) 1. 80-100% (most) =STRONG	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 1. 80-100% (30/32=96%)	1. STRONG

Smith, Ginger, Wright, Wright, Humm, et al. (2014)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation not described, therefore CCT =STRONG	(Q1) Yes. No difference in demographic characteristics and clinical, cognitive, and vocational histories. There were between groups differences in gender and level of major depressive episode. (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Song et al. (2015)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes. No difference in age, gender, and education. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) Yes (Q2) Yes =STRONG	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Thirioux et al. (2014)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	4. Case control Not randomised =MODERATE	(Q1) 1. Yes. No difference in age, gender, and handedness. Other potential confounders not mentioned (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 2. No =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	1. STRONG
Tsang and Man (2013)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	RCT, randomised, randomisation described, method appropriate, therefore RCT =STRONG	(Q1) 1. Yes. No difference in demographic characteristics and baseline outcome measures. There were group differences in gender and illness duration. (Q2) 2. 60-79% (some) =MODERATE	(Q1) 3. Can't tell (Q2) 2. No =MODERATE	(Q1) Yes (Q2) Yes =STRONG	(Q1) 1. Yes (Q2) 2. 60-79% (75/95=79%) =MODERATE	1. STRONG
Bell and Weinstein (2011)	(Q1) 2. Somewhat likely (Q2) 5. Can't tell =MODERATE	5. Cohort	(Q1) 1. Yes. No difference in gender. Differences in age, ethnicity, marital status, and employment. Other potential confounders not mentioned (Q2) 3. Less than 60% (few or none) =WEAK	(Q1) 3. Can't tell (Q2) 3. Can't tell =MODERATE	(Q1) 1. Yes (Q2) 3. Can't tell =MODERATE	(Q1) 4. Not applicable (i.e. one time surveys or interviews) (Q2) 5. Not applicable (i.e. retrospective case-control) =MODERATE	2. MODERATE

KEY: Weak Moderate Strong

2. Using virtual reality to assess associations between paranoid ideation and components of social performance

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ABSTRACT

Background*:** Paranoid ideation and social performance impairments overlap significantly. Virtual reality (VR) can enable assessment of cognitions, emotions, and behaviour in an ecologically valid social environment. This project, in two linked studies, aimed: to recruit a general population sample; test for paranoid ideation and its correlates with cognitive, affective, and behavioural components of social performance (fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress); then to pilot a new VR 'social situation' paradigm in non-clinical participants with high and low paranoid ideation; and to investigate whether fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, and mood are associated with increased paranoid ideation in a VR 'social situation' task. ***Method*:** In Study 1, a general population online survey (N=609) investigated how trait paranoia relates to fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, and mood. In Study 2, two groups were formed based on Study 1 data. Participants who scored high and low in trait paranoia (N=89) entered a VR 'social situation' task to evaluate the acceptability of the new VR paradigm and the relationship between paranoid ideation and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress. ***Results*:** As hypothesised, in Study 1, trait paranoia was associated with fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress; and was consistent with previous findings. As hypothesised, in Study 2, participants found the VR environment acceptable and immersive; exposure to the VR environment elicited fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress; high trait paranoia participants reported higher state paranoia and greater negative CSP in VR. ***Discussion: The VR social situation task has assessment and exposure therapy treatment applications for people with psychosis, who can experience significant paranoia in social situations.

KEYWORDS: virtual reality; social performance; social functioning; paranoia; psychosis

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1. INTRODUCTION

1.1 Social performance and psychosis

There is a well-established link between positive social relationships and good health (Cacioppo & Cacioppo, 2014; House et al., 1988). Meaningful engagement with others has been shown to be an important factor in the pursuit of psychological wellbeing (Schueller & Seligman, 2010); while positive relationships with family, friends, neighbours and colleagues appear to be robustly related to happiness and life satisfaction (Ryan & Deci, 2000). Conversely, the experience of prolonged social isolation and lack of quality social relationships is a major risk factor for developing serious mental health conditions, such as major depression (Teo et al., 2013) and psychosis (de Sousa et al., 2015); abusive parent-child relationships have been associated with the onset of depression, anxiety and post-traumatic stress disorder (PTSD), and psychosis (Bebbington et al., 2004; Fisher et al., 2009), while maternal emotional unavailability in early life was associated with suicide attempts in adolescence (Weich et al., 2009).

Social performance has been demonstrated to involve subcategories of cognitive performance, emotional performance, and behavioural performance. Components of social performance, such as fear of negative evaluation (Leary, 1983), interpersonal sensitivity (Boyce & Parker, 1989), and social avoidance and distress (Watson & Friend, 1969), are indicators of an individual's capacity to initiate and enter into social relationships. Fear of negative evaluation has been defined as apprehension of the prospect of being judged negatively and has been associated with reduced social functioning in schizophrenia (Blanchard et al., 1998); interpersonal sensitivity is a personality trait described as 'excessive awareness of both the behaviour and feelings of others', which has been associated with people at risk of psychosis (Masillo et al., 2012; Masillo et al., 2016); and social avoidance and distress is an indicator of social anxiety and is associated with increased paranoid ideation (Martin & Penn, 2001). Social performance impairments and the experience of social anxiety can have serious effects on role functioning and quality of life (Kessler, 2003). For instance, people who experience high social anxiety have been shown to possess a bias towards identifying others' emotional expressions as negative, thus impairing relationships (Winton et al., 1995); while lack of perceived social acceptance predicts subsequent explicit social anxiety and fear of negative evaluation (Teachman & Allen, 2007).

The onset of psychosis is strongly associated with prolonged experiences of social isolation (Reininghaus et al., 2008), diminished social networks (Garety et al., 2001), impairments in social cognition (Bertrand et al., 2007), and mood disorders (Pini et al., 2001). In particular, a chronic and prolonged experience of social defeat has been shown to increase the risk of schizophrenia (Selten & Cantor-Graae, 2005). As a consequence, interventions that support social relationships, functioning, mood, and performance in the context of psychosis have been shown to be instrumental to subjective recovery (Gayer-Anderson & Morgan, 2013; Tew et al.,

2011) and to improving psychological wellbeing (Schrank et al., 2014). Similarly, family interventions have been shown to have an important role in the treatment of psychosis (Bird et al., 2010; Pilling et al., 2002).

1.2 Paranoid ideation

Paranoid ideation has been conceptualised as a cognitive response to the perception of interpersonal threat (Morrison et al., 2005); and can be understood as a spectrum of beliefs comprising ideas of reference and persecution, related to appraisals of changed and confusing experiences of anomalous internal states (Freeman et al., 2013). Negative judgements about the self, related to paranoid ideation, have been shown to mediate adaptation to the social world (Fowler et al., 2006). Paranoid ideation has implications for psychological wellbeing, mood, functioning, and social inclusion (Freeman et al., 2011); has been shown to be related to insecure attachment styles (Pickering et al., 2008); and can significantly impact on social performance (Combs & Penn, 2004; Gilbert et al., 2005; Valmaggia et al., 2007).

Paranoid ideation is experienced by both clinical and non-clinical populations (Bebbington et al., 2013; Fonseca-Pedrero et al., 2012). It has been hypothesised that paranoid ideation may be as common as symptoms of anxiety and depression: an online study of the general population found that approximately a third of the sample experienced regular paranoid ideation (Freeman et al., 2005). Paranoid ideation has been shown to be associated with the 'jumping to conclusions' reasoning bias in both clinical and non-clinical samples (Freeman & Garety, 2014; Freeman, Pugh, & Garety, 2008). Paranoid ideation and social anxieties have been shown to be highly correlated in people with depression and anxiety: both have been shown to be related to social rank perceptions, power and submissive behaviour (Gilbert et al., 2005), and high rates of mood disorders have been shown in people with psychosis (Freeman & Garety, 2003; Martin & Penn, 2001). Similarly, there is a strong association between paranoid ideation and social stress (Kesting et al., 2013).

People with psychosis commonly experience paranoid ideation (Fowler et al., 2006), which can involve both cognitive (Garety et al., 2015) and emotion-related processes (Bentall et al., 2009). Such dysfunctional negative schemas have been shown to be associated with levels of emotional distress (Garety et al., 2001) and specific delusions can be linked with specific emotions (Freeman & Garety, 2003). Paranoid ideation about the social world may be instrumental to psychosis: studies show that there is a link between trauma and psychosis mediated by negative beliefs about self and others (Gracie et al., 2007); and in one study almost half of the variance in paranoia scores was explained by negative interpersonal self-concepts and the interaction between negative interpersonal self-concepts and dysfunctional acceptance beliefs (Lincoln et al., 2010).

1.3 Virtual reality assessment and treatment in mental healthcare and psychosis

Virtual reality (VR) has been cited as the most fully developed, innovative emerging technology (Thornhill-Miller & Dupont, 2016) and is currently employed in clinical practice to treat cognitive, emotional, and behavioural problems (Bohil et al., 2011; Gregg & Tarrier, 2007; Riva, 2005). Whereas traditional psychological assessment methods employ self-report measures, video feedback, and role-play, which may have limited ecological validity, VR can provide ecologically valid therapeutic environments that enable clinicians to manipulate VR design and real-time environmental conditions (Parsons, 2011). Notable VR innovations in mental health include research and treatments in PTSD (Gonçalves et al., 2012), anxiety disorders (Meyerbröker & Emmelkamp, 2010), specific phobias (Parsons & Rizzo, 2008), eating disorders (Brownley et al., 2007), depression (Falconer et al., 2016), and psychosis (Freeman, 2008; Veling et al., 2014). Optimising validity and efficacy of VR interventions across mental healthcare will depend on immersion or 'sense of presence' (Cummings & Bailenson, 2015; Diemer et al., 2015; Sanchez-Vives & Slater, 2005), reducing side-effects, such as cybersickness (Rosa et al., 2016), and demonstrating acceptability of VR across patient groups.

VR is emerging as a treatment option for psychosis (Freeman, 2008; Veling et al., 2014). Research participants with psychosis have found some immersive VR environments acceptable and experienced few side effects (Fornells-Ambrojo et al., 2008; Freeman, 2008; Stinson et al., 2010) and a very recently published study has shown proof-of-principle evidence of reductions in clinical paranoia following a cognitive therapy exposure to VR environments (Freeman et al., 2016). This offers great potential for clinical practice in psychosis as research has focused on key difficulties such as social impairments and paranoid ideation. Immersive VR social scenarios have been shown to be acceptable and sufficiently realistic for people with psychosis (Veling et al., 2015), while social skills-based interventions that have figured prominently include emotion recognition (Souto et al., 2013), eye gaze (Choi et al., 2010; Han et al., 2014), interpersonal distance (Kim, Ku, et al., 2009), assertiveness (Park et al., 2011), and social cognition (Rus-Calafell et al., 2014). In addition to cognitive and behavioural measures, stress or arousal has also been measured by physiological response, such as heart rate (Allen et al., 2007; Castro et al., 2008; Veling et al., 2015).

The growth of paranoia research has seen the development of psychological treatments (Garety & Freeman, 2013) and measurement tools, such as the Green et al Paranoid Thoughts Scales (GPTS), which was developed for use across the general population-psychopathology continuum (Green et al., 2008), and the State Social Paranoia Scale (SSPS), which measures paranoid ideation about a specific social situation, including VR scenarios (Freeman et al., 2007). VR research in psychosis has targeted auditory hallucinations (Leff et al., 2014; Leff et al., 2013), persecutory delusions (Fornells-Ambrojo et al., 2008), and its relationship with social comparison (Freeman et al., 2014). A strength of VR research has been to provide a controlled

environment in which to assess paranoid ideation (Freeman, Pugh, Antley, et al., 2008; Freeman et al., 2010).

Research on paranoid ideation in social situations has shown that paranoia can be predicted by baseline social defeat (Valmaggia et al., 2015); higher paranoia can impact negatively on interpersonal trust (Fornells-Ambrojo et al., 2016); and heightened sensitivity to environmental social stress may be associated with the onset and course of psychosis (Veling et al., 2016). In both clinical and non-clinical populations, delusional ideation (Kinoshita et al., 2011) is associated with fear of negative evaluation (Watson & Friend, 1969), social distress (Boyce & Parker, 1989), perceived social threat (Taylor & Stopa, 2013), less social engagement, fewer social contacts, and impaired social perception and social skills (Kurtz & Mueser, 2008; Penn et al., 2002). Although social anxiety is a significant comorbidity in psychosis, evidence suggests it is associated with a separate causal pathway (Michail & Birchwood, 2009), indicating that paranoid ideation may impair social performance independently of concurrent social anxiety.

1.4 Study aims

VR interventions for social performance in psychosis have been either non-immersive (Smith, Fleming, Wright, Roberts, et al., 2015) or focused predominantly on one-to-one interactions (Rus-Calafell et al., 2014). The next stage for VR research is to examine the role of cognitive processes, such as paranoid ideation, as well as associated emotional and physiological response (heart rate), within an immersive, interactive, multi-avatar social situation. This will serve as a means to develop real-time therapeutic treatments that target social performance impairments in realistic social settings. This two-part study at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London, aimed to address this need by recruiting non-clinical participants with high and low paranoia and piloting a new VR 'social situation' platform.

In Study 1, the aim was to conduct an online survey of the general population in order to investigate associations between trait paranoia and components of social performance. Given their previous use in psychosis research, as outlined above, components of social performance included cognitive (fear of negative evaluation), affective (social distress), and behavioural (social avoidance) components. Standard measures of mood (depression, anxiety) were also used. In Study 2, the aim was first to form two groups using Study 1 data: then, participants who scored high and low on trait paranoia, as measured by GPTS, were compared to see if a VR social situation task elicited greater feelings of state paranoia, fear of negative evaluation, interpersonal sensitivity, social avoidance and distress, and higher heart rate in people with high trait paranoia. The VR social situation task had not been tested before and so it was important to pilot it with a non-clinical sample to determine the potential for any adverse experiences before it can be used with clinical populations.

Research shows that social media is a viable, efficient, and cost-effective method for recruiting research participants (Fenner et al., 2012; Frandsen et al., 2014; Ramo & Prochaska, 2012; Yuan et al., 2014) but this has yet to be fully demonstrated for a VR study of this kind. Furthermore, studies on paranoia in the general population have used online recruitment effectively (Freeman et al., 2005). Throughout its design and method this study sought to harness new technologies and test the feasibility of their use, employing online programs for recruitment, participant bookings, and data collection in both Studies 1 and 2. A subsidiary aim of this project was therefore to pilot online participant recruitment for a VR study.

The research questions and hypotheses were as follows:

1.5 Research questions

Study 1: Examining the association between trait paranoia and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress

Question 1. Is higher trait paranoia associated with higher levels of fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress and greater negative mood (depression, anxiety) in a non-clinical sample?

Study 2: Using VR to assess paranoid ideation and components of social performance

Question 2. Do participants find the new VR experience acceptable and immersive?

Question 3. Does exposure to the VR environment elicit higher levels of emotional response and increased heart rate?

Question 4. Does higher trait paranoia predict higher state paranoia in the VR environment?

Question 5. Is higher trait paranoia related to higher levels of fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress in the VR environment?

1.6 Hypotheses

Study 1: Examining the association between trait paranoia and components of social performance

Hypothesis 1. Trait paranoia will be associated with higher levels of fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress and greater negative mood (depression, anxiety).

Study 2: Using VR to assess paranoid ideation and components of social performance

Hypothesis 2 The majority of participants will find the new VR experience acceptable and immersive.

Hypothesis 3. Exposure to the VR environment will elicit higher levels of emotional response and increased heart rate.

Hypothesis 4. Higher trait paranoia will be associated with higher state paranoia in VR.

Hypothesis 5. Higher trait paranoia will be related to greater negative CSP in the VR.

2. METHOD

2.1 Design

Study 1 was a cross-sectional cohort study to recruit and establish levels of trait paranoia and associations with fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress and mood in the general population. Study 2 was a cross-sectional comparison study: participants with high and low trait paranoia, recruited from Study 1, were compared to establish levels of state paranoia and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress in a VR social environment.

2.2 Procedure

The study was conducted using the following steps:

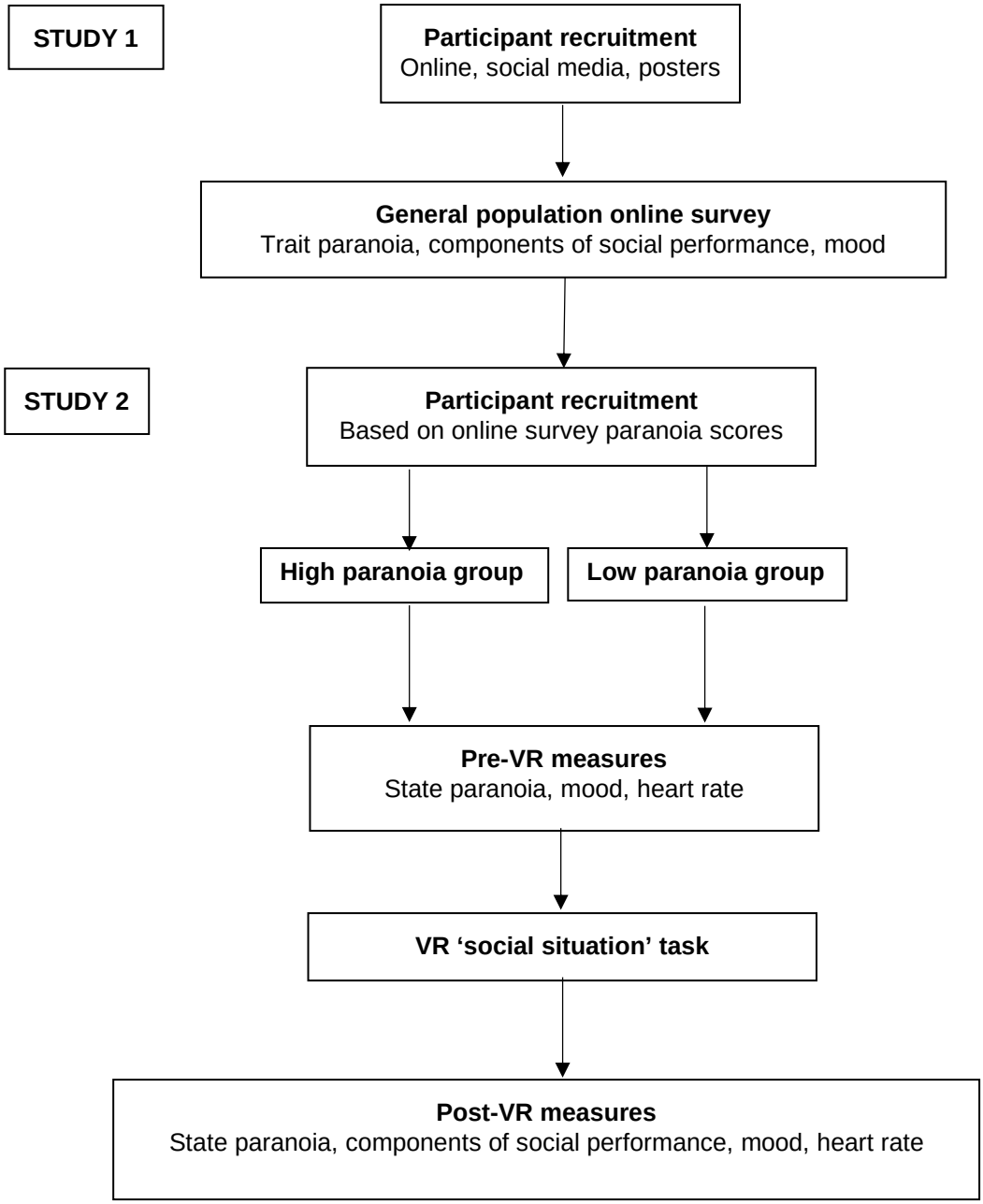

Figure 1. Overview of Study 1 and Study 2 procedure

Figure 1 gives a general overview of the study design. A Method, Results, and brief Discussion section for each of Study 1 and 2 will be presented in sequence below. This will be followed by a Discussion and Overall Summary of both studies. See specific Method sections of Studies 1 and 2 for full details and Figure 3 for a full analysis of Study 2 processes.

2.3 Stakeholder involvement

The study proposal was presented to service user researchers and service users who consult on research at the Service User Advisory Group (SUAG), Biomedical Research Centre (BRC), IoPPN. The SUAG reviewed all stages of the proposal and provided general feedback on applications of VR in mental health assessments and treatments, and specifically for people with psychosis. The SUAG gave a favourable verdict on the study. See Appendix I for a full description of this review.

STUDY 1. ONLINE SURVEY OF PARANOIA IN THE GENERAL POPULATION

3. INTRODUCTION

The aim of Study 1 was to test associations between trait paranoia and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress and mood (depression, anxiety) in the general population using an online survey.

4. METHOD

4.1 Design

This was a cross-sectional cohort study of the general population.

4.2 Procedure

Participants completed an online survey, which was advertised as a survey of thoughts and feelings about social situations. Survey piloting established that the survey took approximately 15-20 minutes and could be completed on any computer, tablet, or smartphone.

4.3 Participants

Participants were working age adults (aged 18-65), fluent English speakers, and willing to be invited to the IoPPN in the event that they were selected for the VR study. Participants were excluded if they reported they had been diagnosed with a serious mental health condition (e.g. psychosis or bipolar disorder), a neurological disorder, learning disability, or epilepsy. People with epilepsy were excluded because there is evidence that an epileptic episode could be triggered by VR exposure. Participants ticked boxes on page 1 of the online survey to confirm that they complied with inclusion and exclusion criteria. Age limits were applied because of the future aim to apply this research to adults (aged 18-65) with psychosis. These age parameters therefore adhere to a convention of how NHS mental health services are organised, i.e. <18 years old; 18-65, and >65.

4.4 Participant recruitment

Participants were recruited online and through social media. Regular bulletins (approximately daily) were posted on Twitter (www.twitter.com). Other Twitter users retweeted these Tweets or were observed to Tweet independently about the study. Additional bulletins were posted to other social media, such as LinkedIn (www.linkedin.com) and Academia.edu (www.adademia.edu); and local web forums, such as The East Dulwich Forum (www.eastdulwichforum.co.uk), craigslist London (www.craigslist.com), and URBAN75 (www.urban75.com). Advertisement emails were twice posted on fortnightly King's College London bulletin email for research studies currently recruiting volunteers. Circular emails were sent to the Psychology Department and the Health Services and Population Research Departments, both King's College London, as well as to other colleagues. Colleagues, friends, and participants offered to circulate advertisements to friends and colleagues by email or social

media, such as Facebook (www.facebook.com). Bulletins and advertisements provided a web link to the online survey. Posters and flyers were distributed around King's College London university buildings and in the local South-East London area.

4.5 Online survey construction

The survey was constructed using Bristol Online Surveys (BOS). BOS is an online survey program that enables development and analysis of surveys via the Web (www.onlinesurveys.ac.uk). Survey settings eliminated the possibility of missing or repeated data. Participants could freely access the survey via a web link on the Internet. See Appendix IV for BOS output of online survey.

4.6 Online survey measures

Demographics. Age, gender, ethnicity, level of education, employment status, relationship/marital status, living arrangements, and way of finding out about the study were recorded. See Appendix IV and data tables for breakdown of each domain.

Green et al. Paranoid Thoughts Scales (GPTS). GPTS measures trait paranoia. It consists of 32 items measured on a 5-point scale, from 1 ('Not at all') to 5 ('Totally'), referring to the past month. Part A consists of 16 items that assess ideas of reference ($GPTS^{REF}$). Part B consists of 16 items that assess ideas of persecution ($GPTS^{PERS}$). Higher total scores for the whole measure ($GPTS^{TOTAL}$) indicate greater levels of paranoid thinking. The minimum total score is 32 and the maximum score is 160. No items are reverse scored. It demonstrates good psychometric properties, with good internal consistency, test–retest reliability (Freeman et al., 2009), and convergent validity with the Paranoia Scale (Fenigstein & Vanable, 1992). Participants were given the following instructions: 'Please read each of the statements carefully. They refer to thoughts and feelings you may have had about others over the last month. Think about the last month and indicate the extent of these feelings from 1 ("not at all") to 5 ("totally"). N.B. Please do not rate items according to any experiences you may have had under the influence of drugs.' A sample item from Part A (Ideas of reference) is 'I spent time thinking about friends gossiping about me'. A sample item from Part B (Ideas of persecution) is 'Certain individuals have had it in for me'.

Social Avoidance and Distress scale (SAD). SAD measures state and trait social avoidance and distress (Watson & Friend, 1969). It consists of 28 items with a response format of 'True' or 'False'. Participants scored 1 for an answer that matched the score key and 0 for an answer that did not match the score key. It demonstrates good psychometric properties, with good construct validity and alpha coefficients (García-López et al., 2001). Participants were given the following instructions: 'The statements below inquire about your personal reactions to a variety of situations. Consider each statement carefully. Then indicate whether the statement is true or

false with regard to your typical behaviour.' A sample item is 'I feel relaxed even in unfamiliar social situations'.

Brief Fear of Negative Evaluation scale (BFNE). BFNE measures apprehension of being negatively evaluated by other people (Leary, 1983). It consists of 12 items measured on a 5-point scale, from 1 ('Not at all characteristic of me') to 5 ('Extremely characteristic of me'). Items 2, 4, 7, and 10 are reverse scored. It demonstrates good psychometric properties that are nearly identical to those of the full-length scale (Watson & Friend, 1969) and correlates significantly with depression and loneliness scales (Duke et al., 2006). Participants were given the following instructions: 'Read each of the following statements carefully and indicate how characteristic it is of you.' A sample item is 'I worry about what other people will think of me even when I know it doesn't make any difference'.

Interpersonal Sensitivity Scale (IPSM). IPSM measures interpersonal sensitivity (Boyce & Parker, 1989). The authors define interpersonal sensitivity as "undue and excessive awareness of and sensitivity to, the behaviour and feelings of others" (p. 342). The measure consists of 36 items measured on a 4-point scale, from 1 ('Very unlike you) to 4 ('Very like you'). No items are reverse scored. IPSM generates a total score as well as five sub-scale scores of interpersonal awareness, need for approval, separation anxiety, timidity and fragile inner-self. It demonstrates good psychometric properties and has been shown to be a valid and reliable instrument for its assessment in social anxiety disorder (Harb et al., 2002). Participants were given the following instructions: 'A number of statements are listed below which relate to how you might feel about yourself and other people in your life. Please indicate with a tick in the appropriate place how each one applies to you – i.e. whether it is "very like you", "moderately like you", "moderately unlike you", or "very unlike you". Respond to each statement in terms of how you are GENERALLY and not necessarily just at present. There are no right or wrong answers.' A sample item is 'I feel insecure when I say goodbye to people'.

Patient Health Questionnaire-8 (PHQ8). PHQ8 measures current depression (Kroenke & Spitzer, 2002). It consists of 8 items measures on a 4-point scale, from 0 ('Not at all') to 3 ('Nearly every day'), referring to the last two weeks. No items are reverse scored. A score ≥10 can be used for defining current depression. It demonstrates good psychometric properties and has been shown to be a useful depression measure for population-based studies, with either its diagnostic algorithm or a cutpoint ≥10 being used for defining current depression (Kroenke et al., 2009). Participants were given the following instructions: 'Over the last 2 weeks, how often have you been bothered by any of the following?' A sample item is 'Little interest or pleasure in doing things'.

Generalised Anxiety Disorder 7 (GAD7). GAD7 measures current generalised anxiety (Spitzer et al., 2006). It consists of 7-items measured on a 4-point scale, from 0 ('Not at all') to 3 ('Nearly

every day'), referring to the last two weeks. No items are reverse scored. It demonstrates good psychometric properties and has been shown to perform well as a measure of anxiety symptom severity (Beard & Björgvinsson, 2014). Participants were given the following instructions: 'Over the last 2 weeks, how often have you been bothered by any of the following?' A sample item is 'Feeling nervous, anxious or on edge'.

Participants also completed the UCLA Loneliness Scale (Peplau & Cutrona, 1980) but this was not included in the present study and was used in another study.

See Appendix IV for BOS output of Online Survey.

4.7 Informed consent

An Information Sheet and Consent Form was integrated within the online survey. Participants consented by typing 'I consent'. Participants could take as much time as needed to decide if they wished to take part and did not have to notify researchers if they decided not to take part.

4.8 Participation incentives

Participants were entered into a prize draw to win one of four £25 Amazon vouchers and informed that they may be invited for the VR study.

4.9 Potential risks

Participants were made aware that the online survey could raise difficult thoughts or feelings. On the final page of the online survey, participants were advised to contact their GP, their local IAPT service, or the Samaritans if the survey raised difficult feelings. Phone numbers and web links were included. See Appendix IV.

4.10 Participant confidentiality

Survey responses were confidential. When completing the online survey, participants were asked to provide a contact email address so they could be contacted for the VR study or the Amazon vouchers. Participants were also given the option of providing their name and a phone number. Participants were made aware that no other identifying information, such as IP address or home address, was collected. All data was stored in a secure, password protected electronic format and contact detail(s) were stored separately from survey data. Participants were identified by a participant number only for all analyses. Participants were assigned a unique, 3-digit participant number based on the order in which they completed the survey (e.g. the third person to complete the survey was 'Participant 003'). Order of online survey completion was selected as it was an arbitrary criterion on which to assign participant numbers. Personal data was only accessible to the research team. Participants were made aware that study results would be used for academic publications and presentations but that all data would be anonymised.

4.11 Freedom to withdraw

Participants were free to withdraw from the study at any time, without giving a reason. If participants decided that they no longer wanted their data to be used after taking part, they were entitled to ask the research team to remove their data from the study. Participants were made aware that there would be no consequences if they withdrew from the study at any time. Partially completed questionnaires were not used.

4.12 Participation benefits

Participants were made aware that the results of the study would inform the future development of a novel and effective assessment and treatment approach to help people with serious mental health problems facing difficulties with social situations.

4.13 Projected sample size

This is a pilot study and, as such, it aimed to recruit sufficient participants to address our research questions concerning feasibility and acceptability and to provide reasonable estimates of key parameters for a future study, rather than determining sample size based on a power calculation using data from previous studies (which are not available) to detect statistically significant differences between groups. An a priori power calculation was therefore not conducted. Based on the GPTS study (Green et al., 2008), which used a similar methodology, this pilot aimed to recruit a minimum of 300 participants to the online survey in Study 1 to ensure a representative spread of paranoia scores; and then, in Study 2, to recruit a subsample of 70 participants from the online survey (35 high paranoia and 35 low paranoia scorers) to take part in the VR task.

4.14 Research approvals

The study was approved by the Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London (Ref: HR-14/15-0859). Approval was also granted by the Clinical Psychology Department, IoPPN.

4.15 Statistical analysis

Analyses were conducted using SPSS, volume 22 (SPSS Inc., Chicago, USA; www.spss.com). Data was explored for normality using histograms, QQ plots, and statistical tests. Nonparametric tests were used as a sensitivity analysis where normality was violated. Internal reliability of scales was calculated using Cronbach's α. Evaluating test-retest reliability of measures was not part of the study. As GPTS data were non-parametric, Spearman's correlation coefficient was used for all correlation analyses. Effect sizes (Spearman's r) were measured at .1 (small effect), .3 (medium effect), and .5 (large effect) (Field, 2009).

5. RESULTS

5.1 Sample characteristics

The online survey was open for two months, from 20 September 2015 to 16 November 2015, during which time 609 people completed the survey. Mean age of participants was 29.33 (SD 9.24, range 18-65). 72% of participants were female. 76% of participants were white. 37% of participants were students and 49% were in fulltime employment. 41% were single and 55% were in a relationship (either cohabiting, non-cohabiting, or married). Table 1 summarises demographic characteristics for the whole sample.

Table 1. Demographic characteristics of online survey sample

Demographic	Whole sample N=609
Age (years)	*Mean (SD, range)*
	29.33 (9.24, 18-65)
Gender	*N (%)*
Male	166 (27.3)
Female	439 (72.1)
Other gender identity	4 (0.7)
Ethnicity	
Asian/Asian British	67 (11)
Black African/Caribbean/British	19 (3.1)
White	463 (76)
Mixed/Multiple ethnic groups	30 (4.9)
Other ethnic group	30 (4.9)
Level of education	
No formal qualifications	1 (0.2)
O-Levels, GCSEs, GCEs	15 (2.5)
AS-, A-levels, (G)NVQ	124 (20.4)
Undergraduate degree	219 (36)
Master's degree	181 (29.7)
Doctorate	69 (11.3)
Employment status	
Student	226 (37.1)
Full-time paid employment	298 (48.9)
Part-time paid employment	47 (7.7)
Full-time unpaid employment	3 (0.5)
Part-time unpaid employment	5 (0.8)
Unemployed	18 (3)
Other employment status	12 (2)
Relationship/marital status	
Single	225 (41)
In a relationship but not cohabiting	112 (18.4)
Cohabiting	127 (20.9)
Married	95 (15.6)
Separated	3 (0.5)
Divorced	8 (1.3)
Widowed	2 (0.3)
Other relationship status	7 (1.1)
Living arrangements	
Live with parents	65 (10.7)
House/flat owner	156 (25.6)
Renting house/flat	223 (36.6)
Renting bedsit	9 (1.5)
Renting room in house share	134 (22)
Staying in hostel	12 (2)
Homeless	1 (0.2)
Other living arrangements status	9 (1.5)

5.2 Recruitment

Overall, 84% of participants found out about the study online or on the Internet. Table 2 summarises the ways participants found out about the study.

Table 2. Participant recruitment sources

Way of finding out about study	N=609
Twitter	71 (11.7)
Facebook	36 (5.9)
Other online social network*	6 (1)
Messaging/chat service**	31 (5.1)
Website	29 (4.8)
Email	304 (49.9)
Online advert	10 (1.6)
Online forum	23 (3.8)
Poster/flyer	15 (2.5)
Verbally informed	55 (9)
Other	25 (4.1)
Prefer not to say	4 (.7)

*not Twitter or Facebook; **E.g. SMS, WhatsApp

5.3 Reliability analysis

All scales and subscales demonstrated adequate internal consistency. Cronbach's α values for the scales are given in Table 3.

Table 3. Internal consistency of scales

Scale	Whole sample α N=609
$GPTS^{REF}$	.929
$GPTS^{PERS}$	.955
$GPTS^{TOTAL}$	.959
SAD	.920
BFNE	.923
ISPM	.895
PHQ8	.880
GAD7	.898

5.4 Paranoia measurement

GPTS scores are given in Table 4.

Table 4. Sample paranoia and components of social performance characteristics

Scale	TOTAL N=609
	Mean (SD, range)
$GPTS^{REF}$	27.60 (11.724, 16-78)
$GPTS^{PERS}$	20.62 (9.768, 16-75)
$GPTS^{TOTAL}$	48.22 (19.84, 32-152)
SAD	9.05 (6.90, 0-28)
BFNE	38.92 (10.527, 12-60)
ISPM	95.13 (14.84, 53-132)
PHQ8	5.66 (5.04, 0-24)
GAD7	5.05 (4.79, 0-21)

The mean (SD) GPTS scores for the present online survey sample ($GPTS^{REF}$=27.60 (11.724); $GPTS^{PERS}$=20.62 (9.768); $GPTS^{TOTAL}$=48.22 (19.84)) were markedly similar to the non-clinical sample in the original GPTS study ($GPTS^{REF}$=26.8 (10.4); $GPTS^{PERS}$=22.1 (9.2); $GPTS^{TOTAL}$ 48.8 (18.7)) (Green et al., 2008).

5.5 Associations between paranoia and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress (Hypothesis 1)

GPTS and its subscales positively correlated with SAD, BFNE, ISPM, PHQ8, and GAD 7. The associations were greater for ideas of reference than persecution. In $GPTS^{TOTAL}$ and $GPTS^{REF}$, effect sizes were large for PHQ8 and GAD7, and medium for SAD, BFNE and ISPM. In $GPTS^{PERS}$, effect sizes were medium for PHQ8 and GAD7, and small for SAD, BFNE and ISPM. Therefore, hypothesis 1, that trait paranoia would be associated with greater fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, was supported. See Table 5.

Table 5. Associations between GPTS, fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, and mood

SCALES	$GPTS^{REF}$	$GPTS^{PERS}$	$GPTS^{TOTAL}$	SAD	BFNE	ISPM	PHQ8	GAD7
$GPTS^{REF}$	-							
$GPTS^{PERS}$	.686*	-						
$GPTS^{TOTAL}$	.981*	.786*	-					
SAD	.335*	.219*	.325*	-				
BFNE	.352*	.158*	.328*	.457*	-			
ISPM	.424*	.257*	.417*	.459*	.751*	-		
PHQ8	.512*	.369*	.512*	.488*	.443*	.526*	-	
GAD7	.499*	.380*	.496*	.485*	.510*	.572*	.786*	-

*Correlation r_s is significant at the .01 level (1-tailed).

5.6 Summary of main findings of Study 1

Participants (N=609) ranged the working age lifespan but were generally younger adults with a mean age in the late twenties. Three quarters of participants were female; three quarters were of white ethnicity; half were in fulltime employment and just over two thirds were students; while just over half were in a relationship. All scales and subscales demonstrated adequate internal consistency. As hypothesised, trait paranoia, and its subscales measuring ideas of reference

and persecution, positively correlated with social avoidance and distress, fear of negative evaluation, interpersonal sensitivity, depression, and generalised anxiety. With trait paranoia and ideas of reference, effect sizes were large for correlations with depression and generalised anxiety, and medium for correlations with social avoidance and distress, fear of negative evaluation, and interpersonal sensitivity. Effect sizes were numerically lower for ideas of persecution when compared with ideas of reference. With ideas of persecution, effect sizes were medium for depression and generalised anxiety, and small for social avoidance and distress, fear of negative evaluation, and interpersonal sensitivity.

6. DISCUSSION

The aim of Study 1 was to test the association between trait paranoia and components of social performance and mood (depression, anxiety) in the general population. The online survey method provided data on levels of paranoid ideation and associated constructs across a broad range of demographics within the general population. The mean GPTS scores were very similar to those of the original GPTS study, which was recruited in person rather than online supporting the findings of the original study. We therefore tentatively conclude that the paranoia scores of this sample are likely to be broadly representative of a general population sample, while using a predominantly online recruitment (though see limitations discussed below). Consistent with previous studies, some degree of paranoid ideation was shown to be common in the general population (Freeman et al., 2005); and further support was given to the thesis that there is a continuum of beliefs in the population, from more to less paranoid ideation, rather than a distinction in kind, between people who experience paranoid ideation and those who do not (Peters et al., 1999).

It was possible to recruit for a VR study online. This was shown to be a time-saving, cost-effective means of recruitment (Kraut et al., 2004). Trait paranoia was associated with fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress and mood, as hypothesised. The study shows that people higher in trait paranoia are more likely to experience social avoidance and distress, fear of negative evaluation, interpersonal sensitivity, depression, and anxiety. These findings build on similar associations with paranoid ideation that have been found in both clinical (Fowler et al., 2011) and non-clinical (Fisher et al., 2012; Martin & Penn, 2001) populations. Results will be discussed in more depth in the General Discussion.

6.1 Strengths

The results add to our understanding of paranoid ideation in the general population. Building on the original GPTS study, they constitute a novel finding for a sample recruited predominantly online. Furthermore, the data provides a clear depiction of how paranoid ideation is associated with a negative impact on fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress; and the consequential impact on psychological wellbeing.

The study confirms that the Internet and social media is a viable and promising method of participant recruitment for VR studies. The growth and increasingly ubiquity of Internet use suggests that web-based recruitment may enable researchers to reach larger and more diverse samples. According to Office of National Statistics data, the internet was accessed every day, or almost every day, by 78% of adults (39.3 million) in Great Britain in 2015, although social networking was used by 61% of adults. These figures are expected to rise in future. Consequently, the present sample is likely to be fairly representative but may also explain the fairly young demographic. The present study also builds on previous studies by not being based on a predominantly student sample (Freeman et al., 2005; Green et al., 2008).

6.2 Limitations

Studies of paranoid ideation in the general population have highlighted limitations of cross-sectional data, insofar as directions of effect cannot be substantiated and associations could be a consequence of other unmeasured variables (Freeman et al., 2011). The present study suffers from similar limitations. In addition, it is possible the present sample was disproportionally interested in VR when compared with the general population, given that the study design included within its initial recruitment a potential invitation for a VR task. Furthermore, despite the demographic diversity, the recruitment strategy still employed some degree of convenience sampling and disproportionately targeted students and university employees within London. Although student numbers still only constituted a minority, this selection bias may have reduced representativeness. It has also been suggested that people who self-select for questionnaires of this type may be more prone to psychological disturbance, or the stigma of appearing to have psychological difficulties might skew the sample in the opposite direction (Freeman et al., 2005). In addition, the gender distribution of participants is notable. There may be a difference in characteristics between those recruited via social media and those recruited in other ways. Selection bias through use of social media could be explored further but it is not possible in the present study due to low numbers of people recruited by other means. Equally, future research might explore social class or economic background in determining how representative a sample recruited predominantly through social media might be. Overall, one should draw epidemiological conclusions with caution.

STUDY 2. VIRTUAL REALITY 'SOCIAL SITUATION' TASK

7. INTRODUCTION

The aim of this study was first to form two groups using Study 1 data: a subsample of participants who scored high and low on trait paranoia, as measured by GPTS, were then compared to see if a VR social situation task elicited greater feelings of state paranoia, mood, fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, and physiological response (heart rate) in those people with higher trait paranoia. The overall aim of this study was to pilot a realistic social situation task that could be applied for clinical use.

8. METHOD

8.1 Design

This was a cross-sectional comparison study with an experimental manipulation: participants with high and low trait paranoia, recruited from Study 1, were compared to establish levels of state paranoia and fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, mood and heart rate, following exposure to a VR social environment.

8.2 Procedure

A subsample of Study 1 participants who were high or low in trait paranoia were recruited. They completed a VR social situation task. Measures of state paranoia, fear of negative evaluation, interpersonal sensitivity, and social avoidance and distress, mood and heart rate were completed pre- and post-VR.

8.3 Participants

Participants were working age adults (aged 18-65), fluent English speakers, who had not been diagnosed with a serious mental health condition, neurological disorder, learning disability, or epilepsy. In order to identify eligible participants for Study 2, total GPTS scores for the online survey sample were placed in ascending order. The higher paranoia sample (HPS) were identified from participants ≥85th percentile. The lower paranoia sample (LPS) were identified from participants ≤15th percentile. These percentiles were chosen as cut-offs at the extreme ends of the ranges of scores and designed to provide a pool from which two large roughly equal subsamples would be selected with significantly different GPTS scores. Once groups were identified, participant number lists for HPS and LPS were each randomised. Randomisation was used to reduce the likelihood of introducing unmeasured confounding variables. Two random samples of 35 participants from both HPS and LPS were identified to be invited for the VR task. Then the two sets of 35 participant numbers were randomised together. Participant identity and contact details were only revealed to the researcher once the HPS and LPS subsamples had been randomised together. This ensured that researchers were blinded to participant group status. Two ordered 'reserve lists' for both HPS and LPS were also identified. If an invited participant was unable or unwilling to attend, a reserve list participant was invited to

replace them. Reserve list participants were invited in batches, which enabled the process of randomisation and blinding to be followed for HPS and LPS reserve list participants. During the VR task, all researchers and participants were blind to participant group status.

A matched pair design using minimisation randomisation was rejected given the relatively small sample size of 35 participants per group. Such a small sample size makes matching according to key demographic criteria difficult while also retaining the two distinct higher and lower paranoia groups. It also risks introducing unmeasured confounding variables by matching according to arbitrarily selected demographic criteria, thus distorting the true sample. Given the limited resources available to the study, a matched pair design was also rejected on pragmatic grounds: the key problem was that a matched pair design would unblind researchers to higher/lower paranoia identities as all higher paranoia participant data would need to be collected before their lower paranoia participant pairs could be identified.

8.4 Participant recruitment

Participants were contacted by email to invite them to take part in the VR task at IoPPN at a time of their convenience. Time slots on weekdays, weekday evenings and weekends were made available and emailed to eligible participants. Appointment scheduling was conducted with Doodle (www.doodle.com/en_GB). Doodle is an Internet calendar tool for time management and coordinating meetings. Participants were able to book their own time slots by accessing Doodle online. Participants were given at least 2 weeks to decide if they wished to participate in the VR study before participants from the reserve list were invited. This recruitment process continued until both higher paranoia VR group (HP-VRG) and lower paranoia VR group (LP-VRG) reached their totals of 35, or until all scheduled appointments were completed.

8.5 Informed consent

Paper Information Sheets and Consent Forms were used for Stage 2. Both documents were emailed to participants in advance of participation. Informed consent was signed for with a researcher present.

8.6 Participant confidentiality

When booking their VR appointments, participants were asked to enter only their unique, 3-digit participant number on a Doodle Poll to reserve a time slot. They did not need to supply any other identifying information. Consent forms were stored in a secure, locked cabinet at the IoPPN and were stored separately from VR data and Study 1 survey data.

8.7 Participation incentives

Participants who attended a VR appointment were paid £10 to compensate for approximately an hour of their time.

8.8 Potential risks

Participants were made aware that some people can experience cybersickness in VR. This was explained in the Information Sheet. The Information Sheet recommended that participants did not drive a car, motorcycle, or use any piece of complicated machinery in the four hours immediately following being in virtual reality. It stated that participants should not drink alcohol or take recreational drugs in the 8 hours before the VR task and reiterated warnings about epileptic episodes. See Appendix VI.

8.9 Freedom to withdraw

Participants were free not to opt in to the VR study and free to withdraw or terminate the VR task at any time without giving a reason.

8.10 VR data collection instruction manual

An instruction manual for VR data collection was developed by SR and finalised in line with training role plays and research team discussion. See Appendix VII.

8.11 Virtual environment

The newly created VR 'social situation' task was a 'party' in a pub, with computer-programmed avatars (Lucia Valmaggia, project lead supervisor, was the lead for a separate study on the design and scripting of the environment). Participants saw images in 3D using a head-mounted display (HMD) and heard sound through headphones. Participants were initially in a street and invited to look around the street, using the joypad to move themselves forward to a mark on the ground. This part of the task served as a demo. Participants were directed to a pub that they were to enter. Participants were told that in the pub they were to look for more marks on the ground and move around the pub according to the marks on the ground. Following a previous study, all participants were given the instruction: 'While you are in the pub please try to get an impression of what the people in the pub think about you and what you think about them. If someone asks you a question, try to reply to them' (Valmaggia et al., 2015). Participants were met by the host of the party who invited them to meet the other guests. Participants experienced one individual greeting and four brief group interactions that were positive, negative or neutral. The environment was populated by female and male avatars. All avatars looked in their 20s or early 30s and different ethnicities (White, Black, Asian) were represented. The initial greeting with the host and the final conversation both had an interactive component where participants were invited to speak out loud in response to questions they were asked by avatars in the VR. At the initial greeting, participants were invited to introduce themselves and then avatars in the pub turned towards them and greeted them in return. At the final conversation, participants were invited to a table by a male avatar. Once at the table, a female avatar asked the participant what their favourite television program was and asked them to tell her about it. Background audio of the people at the party played throughout and had some

ambiguous stimuli with positive (‘she’s so nice’), negative (‘what a loser!’) or neutral interpretations (‘what a joke!’). The scene lasted approximately 5 minutes. See Appendix X for stills of the VR environment.

8.12 Apparatus

Head-mounted display. Participants wore an Oculus Rift Developer version 2 VR headset or head-mounted display (HMD) that gave them a fully immersive, 3D visual experience.

Software. Participants entered a VR street and pub commissioned by King’s College London, designed by software company Virtualware, using the Unity VR platform.

Headphones. Participants wore full-size, noise cancelling headphones that covered and surrounded their ears. These were worn over the top of the HMD.

Control pad. Participants could move themselves forward and backwards in the VR using a computer console control pad with inbuilt joystick. Fluid, 360 degree movement was attained by participants turning their body direction in combination with manipulation of the control pad.

Microphone. Researchers were able to speak in to participants’ headphones with the aid of a microphone.

Desktop computer. An Alienware PC was used by the researcher to run and control the VR scenario.

Tablets. All measures were completed by participants on 7” tablets provided by researchers. Two tablets were used.

Oximeter. Participants wore an oximeter on their forefinger immediately before and immediately after the VR task in order to test heart rate.

8.13 Pre-VR measures

State Paranoia Measure (SPM). SPM is a measure of state paranoia constructed from 7 items tapping state paranoia (Garety et al., 2015). It consists of 6 VAS items on a 10-point scale, from 1 (‘Not at all’) to 10 (‘Totally’). A seventh item, which assesses delusional conviction, was removed for the present study as participants were not being asked to identify a specific delusional thought. SPM demonstrates good psychometric properties (Garety et al., 2015). Participants were given the following instructions: ‘For the following statements, please rate how you feel “right now” from 1 ("not at all") to 10 ("totally")’. A sample item is ‘There is a conspiracy against me’.

Stress, Anxiety, Sadness, and Happiness Visual Analogue Scales (VAS). The VAS consisted of 4 items on a 10-point scale, from 1 (‘Not at all’) to 10 (‘Extremely’). Participants were given the following instructions: ‘For the following questions, please rate how you feel “right now” from 1 ("not at all") to 10 ("extremely")’. A sample item is ‘How stressed do you feel right now?’

Patient Health Questionnaire-8 (PHQ-8). PHQ8 was repeated, as described in ‘Online survey measures’.

Generalised Anxiety Disorder 7 (GAD7). GAD7 was repeated, as described in ‘Online survey measures’.

All measures were completed by participants on a tablet immediately before the VR task.

Heart rate. Heart rate was measured using a finger pulse oximeter to obtain an objective measure of autonomic response. Measurement was recorded by a researcher on a tablet immediately before the VR task.

8.14 Post-VR measures

State Social Paranoia Scale (SSPS). SSPS measures paranoid ideation about a social situation (Freeman et al., 2007). It comprises 20-items measured on a 5-point scale, from 1 (‘Do not agree’) to 5 (Totally agree), with higher scores indicating higher endorsement. In addition to examining persecution (10 items, range 10-50), neutral (5 items, range 5-25) and positive (5 items, range 5-25) ideation about the avatars is explored. No items are reverse scored. SSPS demonstrates good psychometric properties: it has excellent internal reliability, adequate test-retest reliability, clear convergent validity, and showed divergent validity with measures of positive and neutral thinking (Freeman et al., 2007). Participants were given the following instructions: ‘We are interested in your views of the other people who were in the social situation. Please circle how much you agree or disagree with the following statements based upon your thoughts when you were in the social situation’. A sample item is ‘Someone was hostile towards me’.

Visual Analogue Scales (VAS) to measure components of social performance and mood. The 4 Pre-VR VAS were repeated, as described in ‘Pre-VR measures’ to assess stress, anxiety, sadness, and happiness. An additional 11 VAS measured situation-specific paranoia, friendliness of other people, neutrality of other people, hostility of other people, anxiety in the social situation (measuring SAD), desire to avoid social interaction (measuring SAD), fear that other people would disapprove (measuring BFNE), worries of saying or doing the wrong thing (measuring BFNE), how positively or negatively other people were thinking, sense of presence, and enjoyment. The VAS consisted of 15 items on a 10-point scale, from 1 (‘Not at all’) to 10 (‘Extremely’). Participants were given the following instructions: ‘For the following questions,

please rate how you feel “right now” from 1 ("not at all") to 10 ("extremely")’. A sample item is ‘How paranoid did you feel in the social situation?’

Slater-Usoh-Steed Sense of Presence Questionnaire (SUS). SUS measures sense of presence in VR (Slater et al., 1994). It comprises 6 items measured on a 7-point rating scale. SUS demonstrates good psychometric properties for virtual environments (Usoh et al., 2000). Minor modifications to the original measure ensured that it applied to the VR ‘social situation’ used in this study. A sample item is ‘To what extent were there times during the experience when the social situation was the reality for you? "There were times during the experience when the social situation was the reality for me... 1. At no time ... 7. Almost all the time."’

State Paranoia Measure (SPM). SPM was repeated, as described in ‘Pre-VR measures’.

Heart rate. Measurement of heart rate was repeated immediately after the VR task, as described in ‘Pre-VR measures’.

VR experience. To identify potential confounders, participants were asked if they had used VR before and if they played computer games regularly.

Participants also completed a short, audiotaped semi-structured interview designed for measuring persecutory ideation in VR environments (Freeman et al., 2003) but this was not included in the present study and was used in another study. Minor modifications ensured that the measure applied to the VR ‘social situation’.

All measures were completed by participants immediately after the VR task.

8.15 VR task fidelity measures

Task completion. This measure assessed whether participants fully completed the VR task. Post-VR, researchers were asked ‘Did the participant complete the VR task?’ and given options ‘Completed task’, ‘Partially completed task’, or ‘Did not do task’. Partial or non-completion constituted a breach of task fidelity. Participants who partially completed or did not complete the task were excluded from the analysis.

Researcher-participant communication in VR. This measure assessed whether researchers spoke to participants through the microphone during the VR task. Once researchers had fully explained the VR task and equipment to participants, researchers explained to participants that they would not speak to them during the VR task unless they needed to communicate for any reason. The aim was for researchers to optimise participants’ sense of presence in VR by not speaking to participants during the VR task. Researchers only spoke to participants if participants were failing to complete the task or if participants asked the researcher a question.

Post-VR, researchers were asked 'Did you speak to the participant while they were in the pub?' and given options 'Yes' or 'No'. Speaking to participants constituted a minor breach of fidelity with regard to sense of presence. If researchers spoke to participants this was recorded but data were still used in the analysis.

8.16 Researchers

Research assistants received 5 training sessions that covered overview of the study, study documents, the VR task, data collection, and role play of the whole process. See Appendix VII.

8.17 Piloting of measures

Three separate BOS surveys were constructed to host the Pre-VR questions, VR task validity measures, and the Post-VR measures. All surveys were piloted before beginning data collection.

8.18 Participant debriefing

Participants were debriefed on the study after the Post-VR measures were completed. All participants were consulted about any experience of cybersickness. Participants were told that the study was researching paranoia and other emotional responses in VR; that people of higher and lower paranoia had been invited; and that researchers were blinded to participant group identity. Participant questions were answered and Information leaflets that normalise paranoia in the general population were given to participants if necessary. See Appendix XIV for Information leaflet. If participants reported any distressing feelings and felt that they wished to discuss this further, they were signposted to contact their GP. See Appendix VII for full description of debriefing.

8.19 Pilot phase

Previous VR studies have shown that it can be efficacious to incorporate a pilot phase in data collection in order to establish software applications parameters (sound; colour; movement of virtual characters) and to ensure that the VR task runs as intended in order to address research questions (Reid & Campbell, 2006). The pilot phase employed in this study comprised approximately the first 10 participants in the VR task. The aim was that if the VR needed to be modified in line with study requirements after the pilot, then a further 70 participants would be sought and these 10 participants would be excluded from the target of 70.

8.20 Statistical analysis

Analyses were conducted using SPSS, volume 22 (SPSS Inc., Chicago, USA; www.spss.com). Data was explored for normality using histograms, QQ Plots, and statistical tests. Nonparametric tests were used as a sensitivity analysis where normality was violated. Internal reliability of scales was calculated using Cronbach's α. Evaluating test-retest reliability of measures was not part of the study. Demographic differences between groups were calculated

using chi-square tests for categorical data or independent samples t-tests for continuous data. Independent samples t-tests were used to test mean differences between the two groups. Paired samples t-tests were used to test mean differences within the whole group between two time points. Effect sizes (Cohen's d) for independent samples t-tests were calculated using t-values and degrees of freedom, and for paired samples t-tests were calculated using means and standard deviations. Effect sizes were measured at .1 (small effect), .3 (medium effect), and .5 (large effect) (Field, 2009).

9. RESULTS

9.1 Paranoia analysis and sample identification

Ninety-six participants comprised the HPS (≥85th percentile, mean GPTS=86.35) and 100 participants comprised the LPS (≤15th percentile, mean GPTS=32.44). Table 6 summarises HPS and LPS scores for $GPTS^{TOTAL}$, $GPTS^{REF}$, and $GPTS^{PERS}$.

Table 6. High and low paranoia samples' paranoia characteristics

Scale	HPS N=96	LPS N=100	Test	Effect size
	Mean (SD, range)			
$GPTS^{REF}$	47.97 (10.834, 26-78)	16.42 (.496, 16-17)	t(194)=29.091*	.90
$GPTS^{PERS}$	38.39 (14.076, 17-75)	16.02 (.141, 16-17)	t(194)=15.890*	.75
$GPTS^{TOTAL}$	86.35 (20.035, 64-152)	32.44 (.499, 32-33)	t(194)=26.905*	.89

*p<.001 (2-tailed)

All mean group differences were statistically significant with large effect sizes. LPS was tightly clustered whereas the HPS had a wide range. Mean GPTS scores for $GPTS^{PERS}$ (38.39, SD 14.076) and $GPTS^{TOTAL}$ (86.35, SD 20.035) in HPS were lower than $GPTS^{PERS}$ (55.4, 15.7) and $GPTS^{TOTAL}$ (101.9, 29.8) for the clinical sample. See Figure 2.

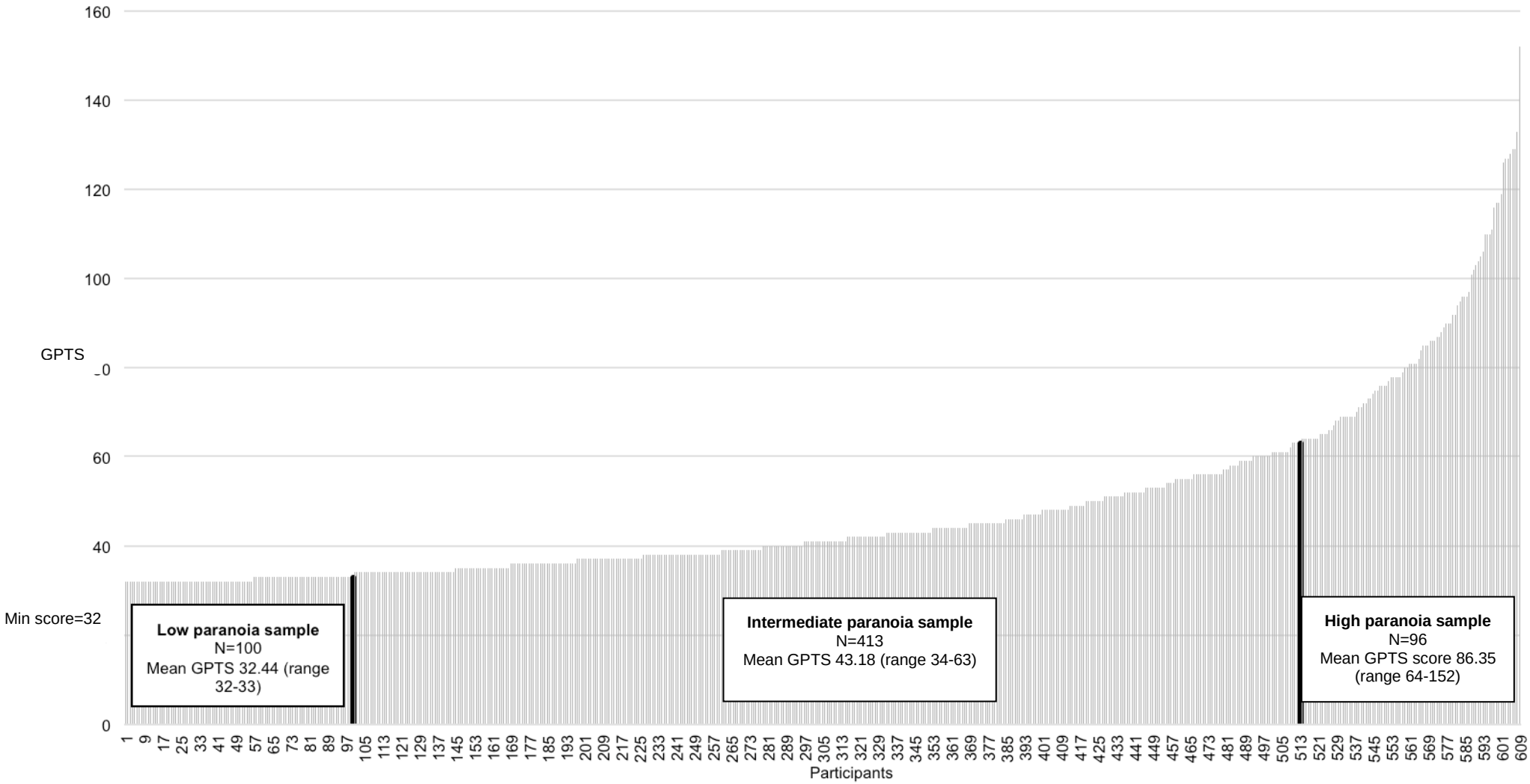

Figure 2. Identification of high paranoia sample (HPS) and low paranoia sample (LPS)

9.2 High and low paranoia sample characteristics

The mean age for HPS was 28.36 (SD 9.793, range 18-62) and for LPS was 34.05 (SD 10.631, range 21-65). Both groups had a similar 2:1 gender ratio in favour of females and large majorities of white ethnicity. Therefore non-white ethnicity categories were collapsed into a single black and minority ethnic (BME). Table 7 summarises demographic characteristics of HPS and LPS.

Table 7. Demographic characteristics of higher and lower paranoia samples

Demographic	HPS N=96	LPS N=100	Test
Age (years)	*Mean (SD, range)*		
	28.36 (9.793, 18-62)	34.05 (10.631, 21-65)	t(194)=-3.890, p<.001 (2-tailed)
Gender	*N (%)*		
Male	31 (32.3)	28 (28)	$X^2(1)=0.3712$, p=.5424
Female	65 (67.7)	71 (71)	
Other gender identity	0 (0)	1 (1)	
Ethnicity			
White	72 (75)	88 (88)	$X^2(1)=5.521$, p<.05
Black and minority ethnic	24 (25)	12 (12)	
Level of education			
Secondary or higher education	34 (35)	13 (13)	$X^2(1)= 27.9888$, p<.00001
Undergraduate degree	39 (40.6)	27 (27)	
Postgraduate degree(s)	23 (24.0)	60 (60)	
Employment status			
Student	38 (39.6)	22 (22)	$X^2(1)=9.1636$, p<.05
In paid employment	48 (50)	71 (71)	
Unpaid/unemployed	10 (10.4)	7 (7)	
Relationship status			
In a relationship	44 (45.8)	69 (69)	$X^2(1)=10.7671$, p<.01
Not in a relationship	52 (54.2)	31 (31)	

The group difference for gender was not statistically significant. Group differences for age, ethnicity, education, employment status, and relationship status were statistically significant..

The majority of participants found out about the study online. Table 8 summarises the ways participants found out about the study.

Table 8. High and low paranoia samples recruitment sources

Way of finding out about study	HPS N=96	LPS N=100	Test
Online	79 (82.3)	77 (77)	$X^2(194)=0.8444$, p=.358
Offline	17 (17.7)	23 (23)	

The group difference in way of finding out about the study was not significant.

9.3 Data collection process

All 96 HPS participant were invited to the VR task and 45 attended: 36 in the high paranoia VR group (HP-VRG), 8 in the pilot, and 1 dropped out during VR task. Seventy-four out of 100 LPS participants were invited to the VR task and 44 attended: 40 in the low paranoia VR group (LP-VRG) and 4 in the pilot.

9.4 Pilot phase

Twelve participants (8 high paranoia, 4 low paranoia) took part in a pilot phase. Participant feedback was used to modify the VR audio to ensure equal quantities of positive, neutral, and negative stimuli. As the VR task was modified, pilot data were not included in the study data and analyses. Researchers and participants were blind to participant group allocation during the pilot phase.

9.5 High and low paranoia VR group paranoia scores

The scores for those who participated in the VR study were as follows: HP-VRG mean GPTS=81.08 and LP-VRG; mean GPTS=32.53. Table 9 summarises HP-VRG and LP-VRG scores for $GPTS^{TOTAL}$, $GPTS^{REF}$, and $GPTS^{PERS}$.

Table 9. High and low paranoia VR group paranoia characteristics

Scale	HP-VRG N=36	LP-VRG N=40	Test	Effect size
	Mean (SD, range)			
$GPTS^{REF}$	44.58 (10.168, 26-78)	16.50 (.506, 16-17)	t(74)=17.457*	.90
$GPTS^{PERS}$	36.50 (11.612, 19-74)	16.03 (.158, 16-17)	t(74)=11.159*	.79
$GPTS^{TOTAL}$	81.08 (18.433, 64-152)	32.53 (.506, 32-33)	t(74)=16.666*	.89

*p<.001 (2-tailed)

All mean group differences were statistically significant with large effect sizes.

9.6 High and low paranoia VR group characteristics

Mean age for HP-VRG was 28.86 (SD 9.84, range 18-54) and for LP-VRG was 33.78 (SD 11.04, range 24-65). Table 10 summarises demographic characteristics for HP-VRG and LP-VRG.

Table 10. Demographic characteristics of high and low paranoia groups in VR study

Demographic	HP-VRG N=36	LP-VRG N=40	Test
Age (years)	*Mean (SD, range)*		
	28.86 (9.84, 18-54)	33.78 (11.04, 24-65)	t(74)=-2.039, p<.05
Gender	*N (%)*		
Male	13 (36.1)	14 (35)	$X^2(1)$=.0102, p=.9195
Female	23 (63.9)	26 (65)	
Other gender identity	0 (0)	0 (0)	
Ethnicity			
White	29 (80.6)	36 (90)	$X^2(1)$=1.3653, p=.243
Black and minority ethnic	7 (19.4)	4 (10)	
Level of education			
Secondary or higher education	10 (27.8)	3 (7.5)	$X^2(1)$=14.084, p<.0001
Undergraduate degree	16 (44.4)	9 (22.5)	
Postgraduate degree(s)	10 (27.8)	28 (70)	
Employment status			
Student	14 (38.9)	9 (22.5)	$X^2(1)$=5.3073, p= .070
In paid employment	17 (47.2)	29 (72.5)	
Unpaid/unemployed	5 (13.9)	2 (5)	
Relationship status			
In a relationship	14 (38.9)	27 (67.5)	$X^2(1)$=6.243, p<.05
Not in a relationship	22 (61.1)	13 (32.5)	

Group differences for gender, ethnicity, and employment status were not statistically significant. Group differences for age, education, and relationship status were statistically significant.

The majority of participants found out about the study online. Table 11 summarises the ways participants found out about the study.

Table 11. VR participant recruitment sources

Way of finding out about study	HP-VRG N=36	LP-VRG N=40	Test
Online	30 (83.3)	30 (75)	$X^2(1)$=0.7917, p=.374
Offline	6 (16.7)	10 (25)	

Group difference in way of finding out about the study were not statistically significant. Table 12 summarises participants' VR and gaming experience.

Table 12. Previous VR and gaming experience of VR participants

VR and gaming experience	HP-VRG N=36	LP-VRG N=40	Test
Previous used VR (%)	11 (30.6)	10 (25.0)	$X^2(1)$=0.2924, p=.589
Play computer games regularly (%)	15 (41.7)	13 (32.5)	$X^2(1)$=1.8456, p=.174

Group differences in VR and gaming experience were not statistically significant.

Figure 3 summarises the Study 2 recruitment and data collection process.

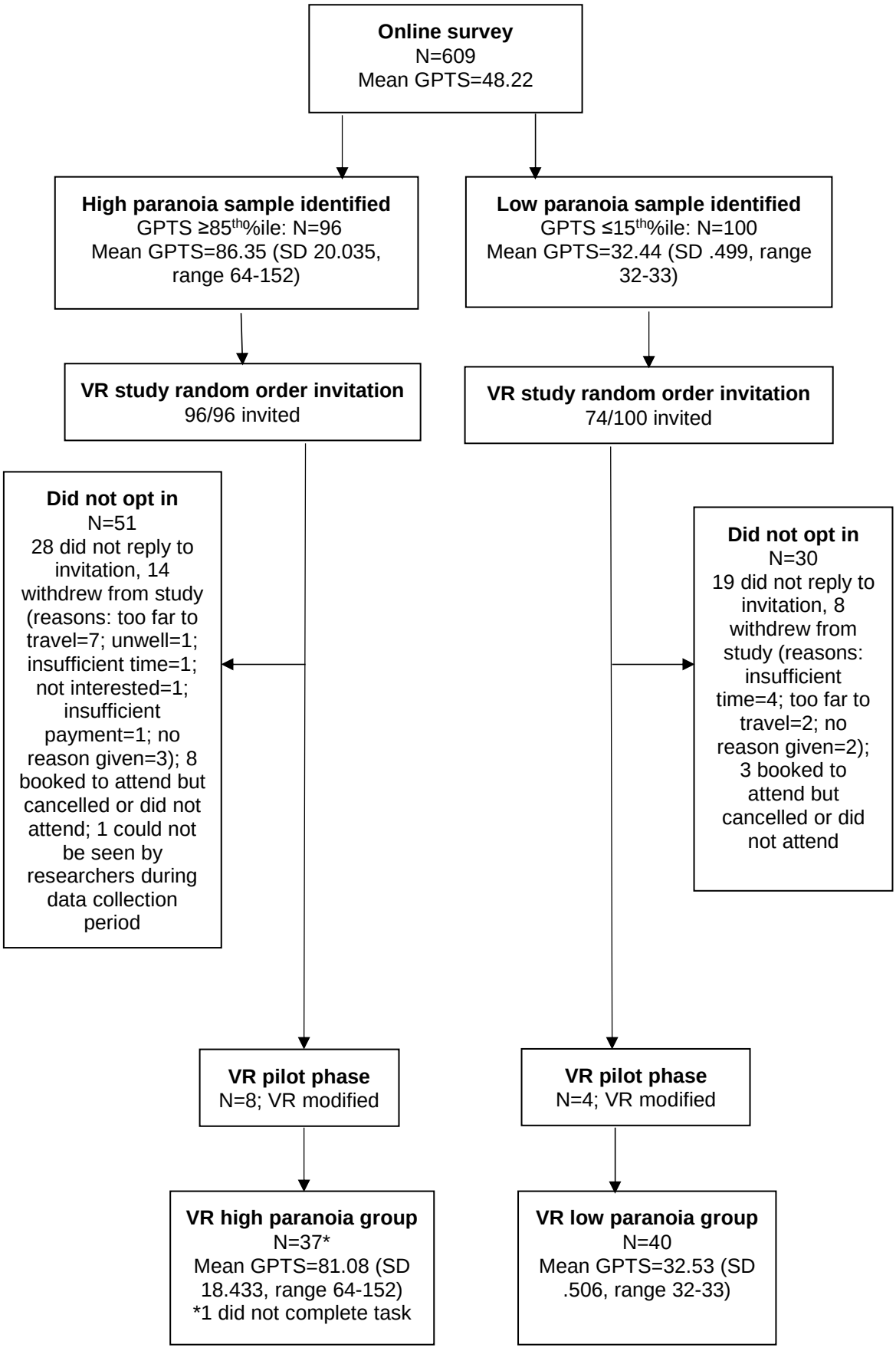

Figure 3. Study 2 recruitment and data collection process

9.7 VR task fidelity

All 76 VR participants completed all parts of the VR task. Data from one additional HP-VRG participant who dropped out before the Pre-VR measures was removed from the analysis. A researcher spoke to participants during the VR task in 18.4% of cases. A researcher speaking to participants during VR was more frequent in the HP-VRG (25%) than in LP-VRG (12.5%). Table 13 summarises VR task fidelity.

Table 13. VR task fidelity

Fidelity	Total sample N=76	HP-VRG N=36	LP-VRG N=40	Test
Participant completed VR task (%)	76 (100)	36 (100)	40 (100)	
Researcher spoke to participant during VR (%)	14 (18.4)	9 (25)	5 (12.5)	$X^2(1)=2.147$, p=0.143

Group differences of task fidelity were not statistically significant.

9.8 Reliability analysis

Cronbach's α values for the scales are given in Table 14.

Table 14. Internal consistency of VR study scales

Scale	HP-VRG N=36	LP-VRG N=40	Total sample N=76
PHQ8	.817	.716	.869
GAD7	.834	.684	.869
SPM^{PreVR}	.853	.191	.869
SPM^{PostVR}	.825	.417	.821
$SSPS^{PERS}$	.919	.827	.913
$SSPS^{POS}$	.581	.732	.717
$SSPS^{NEU}$	.709	.702	.704
SUS	.889	.898	.894

Scales and subscales demonstrated adequate internal consistency for the total sample, apart from SPM, which demonstrated low internal consistency for LP-VRG.

9.9 VR acceptability and sense of presence (Hypothesis 2)

Sense of presence (Immersion) and enjoyment were measured for the whole sample. Independent-samples t-tests compared mean immersion and enjoyment scores between HP-VRG and LP-VRG. See Table 15.

Table 15. VR acceptability and sense of presence

Post-VR scale	Total sample N=76	HP-VRG N=36	LP-VRG N=40	Test	Effect size
	Mean (SD)				
SUS1	4.53 (1.519)	4.61 (1.536)	4.45 (1.518)		
SUS2	3.93 (1.636)	4.03 (1.748)	3.85 (1.545)		
SUS3	4.20 (1.862)	4.19 (1.704)	4.20 (2.015)		
SUS4	4.34 (1.694)	4.33 (1.690)	4.35 (1.718)		
SUS5	4.45 (1.587)	4.42 (1.610)	4.48 (1.585)		
SUS6	3.76 (1.607)	3.81 (1.653)	3.73 (1.585)		
SUS^{TOTAL}	25.21 (8.021)	25.39 (7.980)	25.05 (8.155)	t(74)=.183, p=.856	.02
Presence VAS	6.09 (2.39)	6.17 (2.274)	6.03 (2.516)	t(74)=.256, p=.798	.03
Enjoyment VAS	6.91 (2.246).	6.64 (2.016)	7.15 (2.434)	t(74)=-.99, p=.325	.11

All p-values 2-tailed

Sense of presence and enjoyment were at acceptable levels. Scores were comparable with the original SUS study (Usoh et al., 2000). Group differences were not statistically significant. Therefore, hypothesis 2, that the majority of participants would find the new VR experience acceptable and immersive, was supported.

9.10 VR exposure elicits emotional changes and increased heart rate (Hypothesis 3)

Paired-samples t-tests compared Pre-VR and Post-VR mean VAS scores and heart rate for the whole sample. See Table 16.

Table 16. Pre- and post-VR mood and heart rate

Scale	Pre-VR	Post-VR	Test	Effect size
	Mean (SD)			
Stress VAS	2.57 (1.644)	3.30 (1.987)	t(75)=-3.499**	.40
Anxiety VAS	2.42 (1.56)	3.43 (2.15)	t(75)=-4.809**	.52
Sadness VAS	1.79 (1.236)	2.01 (1.669)	t(75)=-2.06*	.15
Happiness VAS	5.82 (2.108)	5.45 (2.241)	t(75)=-1.746, p=.085	-.17
Heart rate	83.55 (15.431)	86.76 (16.55)	t(75)=-2.131*	.20

*p<.05; **p<.001 (all p-values 2-tailed)

The VR task elicited a statistically significant change in stress (medium effect), anxiety (large effect), sadness (small effect), and heart rate (small effect) for the whole sample. Therefore, hypothesis 3, that exposure to the VR environment would elicit emotional changes and a change in heart rate, was supported.

9.11 Higher paranoia before VR predicts higher paranoia in VR (Hypothesis 4)

An independent-samples t-test compared mean Pre-VR SPM scores between HP-VRG and LP-VRG to evaluate validity of high and low paranoia groupings. There was a significant difference between HP-VRG (10.47, SD 6.25) and LP-VRG (6.15, SD .483); t(74)=4.363, p<.01. Independent-samples t-tests compared mean post-VR paranoia scores between HP-VRG and LP-VRG. See Table 17.

Table 17. Post-VR paranoia scores between HP-VRG and LP-VRG

Post-VR scale	HP-VRG N=36	LP-VRG N=40	Test	Effect size
	Mean (SD)			
SPM	10.39 (6.33)	6.43 (1.43)	t(74)=3.855*	.41
Paranoia VAS	4.78 (2.474)	2.7 (1.757)	t(74)=4.253*	.44
$SSPS^{PERS}$	21.19 (8.998)	14.35 (5.137)	t(74)=4.124*	.43
$SSPS^{POS}$	12.67 (2.859)	15.35 (3.80)	t(74)=-3.448*	.37
$SSPS^{NEU}$	10.92 (3.842)	11.40 (3.727)	t(74)=-.556, p=.58	.06

*p<.001 (all p-values 2-tailed)

Post-VR, HP-VRG were significantly higher in state paranoia (SPM and VAS) and paranoia about the VR social situation (SSPS) than LP-VRG. All had medium effect sizes. Therefore, hypothesis 4, that higher trait paranoia predicts higher state paranoia in VR, was supported.

9.12 High trait paranoia associated with greater negative components of social performance in VR (Hypothesis 5)

Independent-samples tests were conducted to compare Post-VR fear of negative evaluation and social avoidance and distress mean scores between HP-VRG and LP-VRG. See Table 18.

Table 18. Post-VR components of social performance

Post-VR VAS	HP-VRG N=36	LP-VRG N=40	Test	Effect size
	Mean (SD)			
Friendliness of people	3.78 (1.681)	3.98 (1.527)	t(74)=-.543, p=.589	.06
Neutrality of people	4.36 (1.759)	4.68 (1.913)	t(74)=-.742, p=.461	.09
Hostility of people	4.58 (2.02)	4.18 (2.438)	t(74)=.790, p=.432	.09
Socially anxious (SAD)	5.86 (2.416)	4.75 (2.509)	t(74)=1.962, p=.054	.22
Social avoidance (SAD)	5.64 (2.84)	4.08 (2.702)	t(74)=2.459*	.27
Others not approve (BFNE)	4.94 (2.529)	2.98 (2.27)	t(74)=3.578***	.38
Say wrong thing (BFNE)	5.72 (2.7)	4.05 (2.511)	t(74)=2.797**	.31
Others thought of me positively	4.22 (1.758)	4.90 (1.878)	t(74)=-1.619, p=.110	.18

*p<.05; **p<.01; ***p<.001 (all p-values 2-tailed)

HP-VRG were significantly more socially avoidant, more concerned that others would not approve, and more concerned they would say the wrong thing. All had medium effect sizes. Group differences in appraisals of friendliness, neutrality, and hostility of avatars, and of social anxiety were not significant. Therefore, hypothesis 5, that high trait paranoia would be associated with greater negative fear of negative evaluation and social avoidance and distress in VR, was partially supported.

9.13 Summary of main findings of Study 2

High paranoia and low paranoia samples were identified (N=196). Ninety-six of the 96 high paranoia sample were invited to the VR task and 45 attended: 36 in HP-VRG, 8 in the pilot, and 1 dropped out during VR task. Seventy-four of the 100 low paranoia sample were invited to the VR task and 44 attended: 40 in LP-VRG and 4 in the pilot. Mean group differences of trait paranoia were statistically significant with large effect sizes. All 76 VR participants completed all

parts of the VR task. Group differences of task fidelity were not statistically significant. All scales and subscales used in the study demonstrated adequate internal consistency for the total sample, apart from SPM, which demonstrated low internal consistency for LP-VRG. Sense of presence and enjoyment were at acceptable levels. Therefore, the research question about the feasibility and acceptability and the related hypothesis 2, that the majority of participants would find the new VR experience acceptable and immersive, was supported. The VR task elicited a statistically significant change in stress (medium effect), anxiety (large effect), sadness (small effect), and heart rate (small effect) for the whole sample. Therefore, hypothesis 3, that exposure to the VR environment would elicit an emotional response and increased heart rate, was supported. After the VR task, HP-VRG were significantly higher in state paranoia than LP-VRG. All had medium effect sizes. Therefore, hypothesis 4, that higher trait paranoia predicts higher state paranoia in VR, was supported. In the VR task, HP-VRG were significantly more socially avoidant, more concerned that others would not approve, and more concerned they would say the wrong thing. All had medium effect sizes. Therefore, hypothesis 5, that higher trait paranoia would be associated with greater negative CSP in VR, was partially supported. HP-VRG had higher state paranoia and CSP at both pre- and post-VR.

10. DISCUSSION

This study aimed to compare participants of high and low trait paranoia in a VR social situation task to assess whether a VR social situation task would elicit greater feelings of state paranoia, components of social performance, and physiological response in people with high trait paranoia. The VR task was carried out as planned and VR task fidelity was very high. As hypothesised, participants found the VR environment acceptable and immersive. Immersion on SUS was higher in 5/6 items than the virtual reality in a previous study (Usoh et al., 2000). Exposure to the VR environment elicited a range of components of social performance; and high paranoia participants reported higher paranoia in VR. While participants found the VR social situation task somewhat anxiety-provoking, effects sizes for overall stress and sadness elicited by the task were modest. This shows that the VR has the potential to be applied to real-time behavioural experiments with clinicians and can be done so safely.

10.1 Strengths

A key strength of the study is that it explored the link between paranoid ideation and components of social performance in an ecologically valid and standardised VR social environment that has the potential to be manipulated experimentally. Participants found the VR social situation task acceptable. The study controlled for certain potential confounders, such as group differences of gender, ethnicity, employment status, way of finding out about the study, and previous VR or gaming experience, which were not statistically significant.

10.2 Limitations

Group differences of age, education, and relationship status were statistically significant. It is possible that these differences contributed to the effects on components of social performance and paranoia. Low internal consistency on the state paranoia measure (SPM) was notable. It is

possible that some items on the scale reflect more severe paranoia than that experienced by the non-clinical sample used in the present study. A small minority of participants experienced mild cybersickness. However, this was not formally measured in the study so it was not possible to determine if cybersickness was higher in those with high or low paranoia.

11. OVERALL SUMMARY AND GENERAL DISCUSSION

In Study 1, the aim was to conduct an online survey of the general population in order to investigate associations between trait paranoia, as measured by GPTS, and components of social performance. Components of social performance included cognitive (fear of negative evaluation), affective (social distress), and behavioural (social avoidance) components. Standard measures of mood (depression, anxiety) were also used. In Study 2, the aim was two form two groups using Study 1 data: participants who scored higher and lower on trait paranoia, as measured by GPTS, were compared to see if a VR social situation task elicited greater feelings of state paranoia, components of social performance, and physiological response in those people with higher trait paranoia. The study also used new technologies throughout its method: online programs for recruitment, participant bookings, and data collection in both Studies 1 and 2.

Study 2 has shown that trait paranoia was associated with components of social performance; participants in a VR social situation task found the VR environment acceptable and immersive; exposure to the VR environment elicited a range of components of social performance; and higher trait paranoia participants reported higher state paranoia and greater negative components of social performance in VR. The use of technology was shown to be an effective way of recruiting for and conducting the study.

11.1 Clinical implications

This VR study recruited people from the general population with high paranoid ideation. It shows that the VR social situation task has the potential for assessment and treatment applications for people with psychosis, who can experience significant paranoia in social situations. In terms of assessment applications, it shows that VR has the potential to allow clinicians to assess cognitive, behavioural and physiological components of social performance in a controlled environment; and with treatments, it shows that VR has the potential to allow clinicians to conduct ecologically valid exposure work, behavioural experiments, or develop social skills within the safe space of clinical sessions, rather than as homework or through roleplay, and to be able to interact with patients during this process. These potential developments in psychosis could build on effective developments in VR exposure therapy seen in other areas of mental health (Morina et al., 2015; Opriş et al., 2012)

In particular, the positive correlations identified in the present study between trait paranoia and social avoidance and distress, fear of negative evaluation, interpersonal sensitivity, depression, and anxiety all have important clinical applications for treatments in psychosis, where negative cognitions impact negatively on social functioning (Voges & Addington, 2005) and co-morbid

social anxiety is associated with increased shame (Michail & Birchwood, 2009). Firstly, it provides scope for experimental interventions targeted on these specific cognitive, emotional and behavioural correlates in VR and the opportunity to test, under tightly controlled conditions, both whether they can be changed and therefore whether they individually or collectively play a causal or mediating role in paranoia (Freeman & Garety, 2014). Secondly, this study highlights the fact that it will be important for clinicians to conduct a thorough assessment of social functioning impairments when working with people with psychosis and normalise paranoia by acknowledging the ubiquity of paranoid ideation in the general population (Freeman et al., 2005). Finally, VR interventions can provide an ecologically valid environment in which to tackle social avoidance and distress; and to test beliefs about being negatively evaluated. In this sense, VR is a therapeutic tool that may be integrated with existing treatments that target components of social performance in psychosis (Penadés et al., 2006).

11.2 Future research

A future aim is to test the acceptability of the VR social situation task in people with psychosis. Existing VR social skills training packages (Park et al., 2011; Rus-Calafell et al., 2014) can be developed further with greater ecological validity and therapist interaction. A key advancement would be increasing clinicians' capacity to manipulate VR design to target specific processes and real-time environmental conditions. In this regard, psychosis might follow developments in the more advanced field of VR exposure therapy for combat-related PTSD (Reger et al., 2015; Rizzo et al., 2015). Similar studies for psychosis are underway (Freeman et al., 2016; Pot-Kolder et al., 2016).

The findings of this study are consistent with recent VR studies for psychosis that examined social stress (Veling et al., 2016). In testing the VR social situation task used in this study with people with psychosis, it will be important to consider how a clinical sample may differ from the non-clinical sample in the present study, especially with regard to paranoid ideation. In the online survey, mean GPTS scores for $GPTS^{REF}$ in HPS compared significantly with the clinical sample (N=50) in the original GPTS study (Green et al., 2008). By contrast, the mean GPTS scores for $GPTS^{PERS}$ and $GPTS^{TOTAL}$ in HPS were lower than $GPTS^{PERS}$ and $GPTS^{TOTAL}$ for the clinical sample. Therefore, while the sample in HPS was comparable to a psychosis sample in terms of ideas of reference, it was lower in terms of persecutory beliefs. Given the very wide range of our HPS there is overlap with clinical scores and some of HPS had total scores in the clinical range (one SD of our total scores are at the clinical mean) suggesting that it can be taken as a partial comparator to a clinical sample. It is notable that no adverse effects were reported in the present study, also suggesting that this is a safe intervention. However, a future study involving participants with psychosis should be aware that persecutory beliefs may be higher than were found in the present sample.

Future research into paranoid ideation might investigate in greater depth its phenomenological properties and its relationship to emotional concerns. These data support Freeman and colleagues' hypothesised hierarchical arrangement of paranoid ideation that builds on common

emotional concerns, noting that our high paranoia non-clinical sample scored more highly on ideas of reference which are less severe and more common concerns than persecution (Freeman et al., 2005). The range of components of social performance was necessarily limited due to study resources; however, further associations that might be explored in order to develop our understanding of paranoid ideation in social situations may include self-esteem (Thewissen et al., 2008) and emotion dysregulation (Westermann et al., 2012).

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Appendix I Service user review

BRC Service User Advisory Group review, IoPPN, 6th August 2014 – Notes on meeting by SR

The Service User Advisory Group felt that VR interventions could be very useful in clinical practice. Members of the group reported that the flexibility of the therapeutic setting would be a particular advantage and that this opened doors to having therapeutic sessions in a variety of contexts. In particular, members of the group identified exposure therapy in anxiety and phobias as particularly useful ways to employ this technology, given the fact that VR would allow clients to be put into settings that would otherwise be difficult or impossible to achieve. In general, they felt that the VR could be a useful tool for giving clients positive experiences. Several members of the group disclosed that they had a diagnosis of psychosis and had always found it extremely challenging to conjure up mental imagery when asked to do so by a therapist. These group members reported that a VR intervention could be very useful to them if VR could act as a proxy for mental imagery.

The group highlighted that VR would provide the opportunity to replay, rerun, or pause behavioural experiments. They felt that the therapist as avatar would be useful to consult and as a source of support if they were in the VR environment together during this process. In general they found the idea of the therapist entering the VR to be an acceptable and even a helpful one. One group member felt that the therapist moving from the real world into the VR and clearly identifying themselves would be comforting and would retain the idea of feeling like you were talking to a real person. This was contrasted with the scenario in the Avatar study which, the group member felt, could be alarming for some participants and would not feel like they were talking to a real person.

In terms of the study information sheets, the group suggested that it would be important to be clear that the technology, and therefore the specific features of the virtual environment, is completely under the control of the researcher, and therefore also the participants. In other words, all events that occurred in the virtual environment would be known by the researcher in advance and could be explained to the participant. In terms of study design, the group felt it would be useful to ask participants at the outset about their level of presence in ordinary life. Suggested examples included how present/immersed participants felt playing computer games and watching films or television.

The group were keen to see how immersive the virtual reality technology could be and stated that they did not feel that the VR avatars needed to be too real in order for presence to be felt. The group found it acceptable that the therapist avatar could bear a reasonable resemblance to the actual therapist. They found it acceptable that this could be achieved with gender, similar build, and clothing. In this regard, one member of the group referenced the thesis of the ‘uncanny valley’ which, in this context, might suggest that some participants may recoil if avatars are too lifelike and that an approximate likeness may be preferable.

Several members, who disclosed that they had a diagnosis of psychosis, stated that they would be keen to pilot the technology.

Appendix II Research Ethics Committee documents

Dr Simon Riches

King's College London, Institute of Psychiatry, Psychology & Neuroscience
Department of Psychology, De Crespigny Park
London
UK
SE5 8AF

24 July 2015

Dear Simon,

Reference Number: LRS-14/15-0859

Study Title: Using virtual reality to improve the assessment of social performance

Review Outcome: Approved pending amendments/clarifications

Thank you for submitting the above application for ethical approval. Your application has been reviewed and and has been approved pending amendments. You are now required to address a number of issues before full approval is granted. These are specified in the feedback table below. Please respond to each point raised by the Committee and amend your application form, and appendices, accordingly.

In order to amend the application, you will simply need to log on onto REMAS and modify the existing application. Once again, your academic supervisor will be required to provide verification. The amended application will be reviewed by Chair's action rather than by the full Committee.

If for some reason you choose not to proceed with this research ethics application, please inform the Research Ethics Office .

Please note that research involving human participants must not commence until full ethical approval has been granted.

Yours sincerely,

James Patterson - Senior Research Ethics Officer

For and on behalf of

Professor Gareth Barker, Chair

Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

Cc: Lucia Valmaggia

Review Reference: LRS-14/15-0859

Period of Approval requested: 3 years

Approved in principle

Major issues (will require substantial consideration by the applicant before approval can be granted)

1. Section F1 - Question 4d: Given the nature of the study, your answer should be 'yes'. This will re-designate your study appropriately as a 'high-risk' study. Please complete the additional fields that will be generated automatically.

Minor issues related to application (the reviewer should identify the relevant section number before each comment)

2. Section C1: Justify or remove the upper age limit.

3. Stage 1 questionnaire:

i. Use UK Census 2011 categories of ethnicity.

ii. Please enable participants to give *explicit* consent, required by the Data Protection Act (1998) for sensitive personal data such as this. This might, for example, involve participants typing 'I consent' into an appropriate field.

Minor issues related to recruitment documents

4. Information Sheet:

i. Use the standard introductory paragraph for College information sheets.

ii. Clarify that the study is being conducted for a PhD at King's College London.

iii. Expand briefly upon the virtual reality element of study.

iv. Clarify the process for withdrawal of participant data.

v. Clarify whether partially completed questionnaires will be used.

vi. Remove the paragraph entitled 'What if something goes wrong'.

vi. Insert the paragraph beginning with 'If this study has harmed you in any way...' before the contact details for your academic supervisor.

vii. Replace 'King's College London Research Ethics Committee' with 'Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London'.

Advice and Comments (do not have to be adhered to, but may help to improve the research)

5. Sections B2 and B3: Please note that ethical approval for PhD studies is normally granted for a period of three years.

Simon Riches

27 August 2015

Dear Simon ,

Study Title: Using virtual reality to improve the assessment of social performance

Study Reference: HR-14/15-0839

I am pleased to inform you that full approval for your project has been granted by the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information, ethical approval is granted until 27 August 2018. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed. If you have been granted approval for only 12 months, you will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

For secondary data-analysis, ethical approval is applicable to the data that is sensitive or identifies participants.

Approval is applicable to period in which such data is accessed or evaluated.

Please note you are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(http://www.kcl.ac.uk/innovation/research/support/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

James Patterson - Senior Research Ethics Officer

For and on behalf of

Chair of the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

Cc: Lucia Valmaggia

Site Logo

Full Application Form

Filter Questions

1 Is your study considered research as defined in the guidance icon information?
- (•) Yes
- ( ) No

2 Does this research require ethical review by an NRES REC? (Please refer to the information in the guidance icon for further details on what research requires NRES REC review)
- ( ) Yes
- (•) No

Data Collection

3 Select one category from the list below (categories are defined in the guidance icon).

My study involves:
- (•) a) Only primary data collection involving human subjects.
- ( ) b) Only further analysis of pre-existing data (originally obtained from human participants) which is sensitive or identifiable and not in the public domain.
- ( ) c) Both primary data collection involving human subjects and further analysis of pre-existing (originally obtained from human participants) data which is sensitive or identifiable and not in the public domain
- ( ) d) Data collection not involving any of the above but presenting sensitive issues
- ( ) e) None of the above

4 Select all that apply in order to determine the risk level of your application.
- [ ] a) Does the research involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position?
- [ ] b) Will participants be asked to take part in the study without their consent or knowledge at the time or will deception of any sort be involved?
- [ ] c) Is there a risk that the research topic might lead to disclosures from the participant concerning their involvement in illegal activities or other activities that represent a threat to themselves or others?
- [x] d) Could the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in normal life?
- [ ] e) Does the study involve imaging techniques such as MRI scans or ultrasound?
- [ ] f) Does the study involve sources of non-ionising radiation (e.g. lasers)?
- [ ] g) Does the study involve physically intrusive procedures, use of bodily materials, or DNA/RNA analysis? (including collection of human tissue)

Appendix III Study 1 recruitment tools

Sample online bulletin text – long

"VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

This is a study in two stages taking place at the Institute of Psychiatry, Psychology & Neuroscience, King's College London.

Stage 1: Online Survey

An online survey of working age adults is being carried out to understand the thoughts and feelings that people experience, especially about social situations. It takes approximately 30 minutes and can be completed on any computer or handheld device. Everyone who completes the survey will be entered into a prize draw to win one of four £25 Amazon vouchers. The survey data will then be analysed to improve our understanding of how people think and feel about social situations.

Stage 2: Virtual Reality

A selection of those who complete the survey will be invited to take part in a virtual reality study at the Institute of Psychiatry, Psychology & Neuroscience. This will involve piloting a new virtual reality platform and aims to understand how people respond when entering a social environment in virtual reality. The results of the study will inform the future development of a novel and effective assessment and treatment approach to help people with serious mental health problems facing difficulties with social situations.

Click here to enter the online survey [Link to survey]."

Sample online bulletin text – brief

"Recruiting participants for new #VirtualReality study @Kingspsychol @KingsIoPPN in #London. Fill in survey to enter [Link to survey]"

An example forum for a brief online bulletin would be Twitter.

Want to take part in a

VIRTUAL REALITY

research study?

We are looking for study participants

at **King's College London**

Enter the study here

https://kings.onlinesurveys.ac.uk/vrandsocialsituations

Find the study on Twitter @sjriches

Want to take part in a

VIRTUAL REALITY

research study?

We are looking for study participants

at King's College London

Enter the study here

https://kings.onlinesurveys.ac.uk/vrandsocialsituations

Find the study on Twitter @sjriches

VIRTUAL REALITY study https://kings.onlinesurveys.ac.uk/vrandsocialsituations

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Appendix IV Study 1 online survey BOS output, information sheet, and consent form

KING'S College LONDON

University of London

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY - ONLINE SURVEY

Page 1: WELCOME

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

INFORMATION SHEET FOR ONLINE SURVEY

We would like to invite you to participate in this original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

About the study

This is a study in two stages, which forms part of a doctoral degree at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London.

Stage 1: Online Survey

An online survey of working age adults is being carried out to understand the thoughts and feelings that people experience, especially about social situations. It takes approximately 15-20 minutes and can be completed on any computer, tablet, or smartphone. ('Tableless mode' may be preferable for smaller devices.) Everyone who completes the survey will be entered into a prize draw to win one of four £25 Amazon vouchers. The survey data will then be analysed to improve our understanding of how people think and feel about social situations.

Stage 2: Virtual Reality

A selection of those who complete the survey will be invited to take part in a virtual reality study at the IoPPN. This will involve piloting a new virtual reality platform and aims to understand how people respond when entering a social environment in virtual reality. If you choose to accept this invitation, you will be paid £10 for approximately 1 hour of your time.

Eligibility

Any working age adult (aged 18-65), who is fluent in English, and willing to be invited to the IoPPN (Denmark Hill, South East London) at a time convenient to them, between November 2015 and February 2016, is invited to take part in the survey. Unfortunately we do not have the required approvals to use the virtual reality equipment with anyone outside the working age bracket, or anyone who has ever been diagnosed with a serious mental health problem (e.g. psychosis or bipolar disorder), a neurological disorder, a learning disability, or epilepsy. Therefore we will not be able to include people from these groups in the study.

Confidentiality

Your responses will be confidential. We will ask for a contact email address in case we need to contact you for the virtual reality study or the Amazon vouchers. We will also ask for your name and a phone number but providing this information is optional. We do not collect any other identifying information such as your IP address or your home address. All data is stored in a password protected electronic format. When data is downloaded to a secure file, your contact detail(s) will be kept separate from your survey data and you will be identified by a participant number. The results of this study will be used for academic publications and presentations but all data will be anonymised.

Research Aims

The results of the study will inform the future development of a novel and effective assessment and treatment approach to help people with serious mental health problems facing difficulties with social situations.

Ethical Approval

This study has been approved by the Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London (Ref: HR-14/15-0859).

Your Right to Withdraw

You are free to withdraw from this study at any time. Before you begin the survey, we will ask you to complete a brief consent form to ensure that you are eligible and understand what is involved in the study. However, there will be no consequences if you choose to withdraw from the study at any time. You will just need to contact the research team to let us know if you do not want your data to be used. Partially completed questionnaires will not be used. If you are invited for the virtual reality study, you are free to decline this invitation.

Contact

If you have any questions about the research, please contact Dr Simon Riches or Dr Lucia Valmaggia:

Dr Simon Riches

King's College London

Institute of Psychiatry, Psychology & Neuroscience (PO78)

De Crespigny Park, Denmark Hill

London SE5 8AF, UK

Simon.s.riches@kcl.ac.uk

Dr Lucia Valmaggia

Scientific Advisor Virtual Reality Lab

King's College London

Institute of Psychiatry, Psychology & Neuroscience

Department of Psychology (PO77)

De Crespigny Park, Denmark Hill

London SE5 8AF, UK

Lucia.valmaggia@kcl.ac.uk

If you would like to take part in the online survey, the

next page will take you to the Consent Form.

Page 2: CONSENT FORM

Please confirm that you have read the Information Sheet about the study (on the previous page).

- I have read the Information Sheet

Please confirm that you are a working age adult, i.e. your age is between 18 and 65.

- I am a working age adult (aged 18-65)

Please confirm that you are a fluent speaker of English.

- I am a fluent speaker of English

Please confirm that you are willing to be invited to take part in the virtual reality study at the Institute of Psychiatry, Psychology and Neuroscience (for an appointment that is convenient to you between November 2015 and February 2016).

- I am willing to be invited to the Institute of Psychiatry, Psychology and Neuroscience for the virtual reality study

Please confirm that you have not been diagnosed with a serious mental health problem (e.g. psychosis or bipolar disorder), a neurological disorder, a learning disability, or epilepsy.

○ I have not been diagnosed with a serious mental health problem, a neurological disorder, a learning disability, or epilepsy

Please type the words 'I consent' in the box below to confirm that you consent to taking part in this survey.

Consent Form 1 (Online Survey) (Version 2, date: 10/8/2015)

Page 3: GENERAL INFORMATION

We would be very grateful to find out some general information about you.

What is your age?

○ 18	○ 19	○ 20
○ 21	○ 22	○ 23
○ 24	○ 25	○ 26
○ 27	○ 28	○ 29
○ 30	○ 31	○ 32
○ 33	○ 34	○ 35
○ 36	○ 37	○ 38
○ 39	○ 40	○ 41
○ 42	○ 43	○ 44
○ 45	○ 46	○ 47
○ 48	○ 49	○ 50
○ 51	○ 52	○ 53
○ 54	○ 55	○ 56
○ 57	○ 58	○ 59
○ 60	○ 61	○ 62
○ 63	○ 64	○ 65

How would you describe your gender?

- ○ Male
- ○ Female
- ○ Other

Which of the following best describes your employment status?

- Student
- Part-time PAID employment
- Full-time PAID employment
- Part-time UNPAID employment
- Full-time UNPAID employment
- Unemployed
- Other

Which of the following best describes your marital/relationship status?

- Single
- In a relationship but not cohabiting
- Cohabiting
- Married
- Separated
- Divorced
- Widowed
- Other

Which of the following best describes your current living arrangements?

- I live with my parents
- I own the house/flat where I'm living
- I'm renting a house/flat

- I'm renting a bed-sit
- I'm renting a room in a house share
- I'm staying in a hostel
- I'm homeless
- Other

Which of the following best describes your highest academic achievement?

- No formal qualifications
- O-Levels, GCSEs, GCEs
- AS-, A-levels, (G)NVQ
- Undergraduate degree
- Masters degree
- Doctorate

Which of the following best describes your ethnicity?

- Asian/Asian British
- Black/ African/Caribbean/Black British
- White
- Mixed/Multiple ethnic groups
- Other ethnic group

Page 4: SADS-28

The statements below inquire about your personal reactions to a variety of situations. Consider each statement carefully. Then indicate whether the statement is true or false with regard to your typical behaviour.

	True	False
1. I feel relaxed even in unfamiliar social situations	☐	☐
2. I try to avoid situations which force me to be sociable	☐	☐
3. It is easy for me to relax when I am with strangers	☐	☐
4. I have no particular desire to avoid people	☐	☐
5. I often find social occasions upsetting	☐	☐
6. I usually feel calm and comfortable at social occasions	☐	☐
7. I am usually at ease when talking to someone of the opposite sex	☐	☐
8. I try to avoid talking to people unless I know them well	☐	☐
9. If the chance comes to meet new people, I often take it	☐	☐
10. I often feel nervous or tense in casual get-togethers in which both sexes are present	☐	☐
11. I am usually nervous with people unless I know them well	☐	☐
12. I usually feel relaxed when I am with a group of people	☐	☐
13. I often want to get away from people	☐	☐
14. I usually feel uncomfortable when I am in a group of people I don't know	☐	☐
15. I usually feel relaxed when I meet someone for the first time	☐	☐
16. Being introduced to people makes me tense and nervous	☐	☐
17. Even though a room is full of strangers, I may enter it anyway	☐	☐

18. I would avoid walking up and joining a large group of people	☐	☐
19. When my superiors want to talk with me, I talk willingly	☐	☐
20. I often feel on edge when I am with a group of people	☐	☐
21. I tend to withdraw from people	☐	☐
22. I don't mind talking to people at parties or social gatherings	☐	☐
23. I am seldom at ease in a large group of people	☐	☐
24. I often think up excuses in order to avoid social engagements	☐	☐
25. I sometimes take the responsibility for introducing people to each other	☐	☐
26. I try to avoid formal social occasions	☐	☐
27. I usually go to whatever social engagements I have	☐	☐
28. I find it easy to relax with other people	☐	☐

SADS-28 (Version 1, date: 1/6/2015)

Page 5: BFNES-12

Read each of the following statements carefully and indicate how characteristic it is of you.

	Not at all characteristic of me	Slightly characteristic of me	Moderately characteristic of me	Very characteristic of me	Extremely characteristic of me
1. I worry about what other people will think of me even when I know it doesn't make any difference	☐	☐	☐	☐	☐
2. I am unconcerned even if I know people are forming an unfavourable impression of me	☐	☐	☐	☐	☐
3. I am frequently afraid of other people noticing my shortcomings	☐	☐	☐	☐	☐
4. I rarely worry about what kind of impression I am making on someone	☐	☐	☐	☐	☐

5. I am afraid others will not approve of me	☐	☐	☐	☐	☐
6. I am afraid that people will find fault with me	☐	☐	☐	☐	☐
7. Other people's opinions of me do not bother me	☐	☐	☐	☐	☐
8. When I am talking to someone, I worry about what they may be thinking about me	☐	☐	☐	☐	☐
9. I am usually worried about what kind of impression I make	☐	☐	☐	☐	☐
10. If I know someone is judging me, it has little effect on me	☐	☐	☐	☐	☐
11. Sometimes I think I am too concerned with what other people think of me	☐	☐	☐	☐	☐

12. I often worry that I will say or do the wrong things	☐	☐	☐	☐	☐

Page 6: IPSM-36

A number of statements are listed below which relate to how you might feel about yourself and other people in your life. Please indicate with a tick in the appropriate place how each one applies to you – i.e. whether it is "very like you", "moderately like you", "moderately unlike you", or "very unlike you". Respond to each statement in terms of how you are GENERALLY and not necessarily just at present. There are no right or wrong answers.

	Very like you	Moderately like you	Moderately unlike you	Very unlike you
1. I feel insecure when I say goodbye to people	☐	☐	☐	☐
2. I worry about the effect I have on other people	☐	☐	☐	☐
3. I avoid saying what I think for fear of being rejected	☐	☐	☐	☐
4. I feel uneasy meeting new people	☐	☐	☐	☐
5. If others knew the real me they would not like me	☐	☐	☐	☐
6. I feel secure when I'm in a close relationship	☐	☐	☐	☐
7. I don't get angry with people for fear that I may hurt them	☐	☐	☐	☐
8. After a fight with a friend, I feel uncomfortable until I have made peace	☐	☐	☐	☐
9. I'm always aware of how other people feel	☐	☐	☐	☐

10. I worry about being criticized for things I have said or done	☐	☐	☐	☐
11. I always notice if someone doesn't respond to me	☐	☐	☐	☐
12. I worry about losing someone close to me	☐	☐	☐	☐
13. I feel that people generally like me	☐	☐	☐	☐
14. I will do something I don't want to rather than offend or upset someone	☐	☐	☐	☐
15. I can only believe that something I have done is good when someone tells me it is	☐	☐	☐	☐
16. I will go out of my way to please someone I am close to	☐	☐	☐	☐
17. I feel anxious when I say goodbye to people	☐	☐	☐	☐
18. I feel happy when someone compliments me	☐	☐	☐	☐
19. I fear that my feelings will overwhelm people	☐	☐	☐	☐
20. I can make other people feel happy	☐	☐	☐	☐
21. I find it hard to get angry with people	☐	☐	☐	☐
22. I worry about criticizing other people	☐	☐	☐	☐
23. If someone is critical of something I do, I feel bad	☐	☐	☐	☐
24. If other people knew what I am really like, they would think less of me	☐	☐	☐	☐
25. I always expect criticism	☐	☐	☐	☐
26. I can never be really sure if someone is pleased with me	☐	☐	☐	☐

27. I don't like people to really know me	☐	☐	☐	☐
28. If someone upsets me, I am not able to put it easily out of my mind	☐	☐	☐	☐
29. I feel others do not understand me	☐	☐	☐	☐
30. I worry about what others think of me	☐	☐	☐	☐
31. I don't feel happy unless people I know admire me	☐	☐	☐	☐
32. I am never rude to anyone	☐	☐	☐	☐
33. I worry about hurting the feelings of other people	☐	☐	☐	☐
34. I feel hurt when someone is angry with me	☐	☐	☐	☐
35. My value as a person depends enormously on what others think of me	☐	☐	☐	☐
36. I care about what people feel about me	☐	☐	☐	☐

IPSM-36 (Version 1, date: 1/6/2015)

Page 7: GPTS-32

Please read each of the statements carefully. They refer to thoughts and feelings you may have had about others over the last month. Think about the last month and indicate the extent of these feelings from 1 ("not at all") to 5 ("totally"). N.B. Please do not rate items according to any experiences you may have had under the influence of drugs.

	1 (Not at all)	2	3 (Somewhat)	4	5 (Totally)
1. I spent time thinking about friends gossiping about me	☐	☐	☐	☐	☐
2. I often heard people referring to me	☐	☐	☐	☐	☐
3. I have been upset by friends and colleagues judging me critically	☐	☐	☐	☐	☐
4. People definitely laughed at me behind my back	☐	☐	☐	☐	☐
5. I have been thinking a lot about people avoiding me	☐	☐	☐	☐	☐
6. People have been dropping hints for me	☐	☐	☐	☐	☐
7. I believed that certain people were not what they seemed	☐	☐	☐	☐	☐

8. People talking about me behind my back upset me	☐	☐	☐	☐	☐
9. I was convinced that people were singling me out	☐	☐	☐	☐	☐
10. I was certain that people have followed me	☐	☐	☐	☐	☐
11. Certain people were hostile towards me personally	☐	☐	☐	☐	☐
12. People have been checking up on me	☐	☐	☐	☐	☐
13. I was stressed out by people watching me	☐	☐	☐	☐	☐
14. I was frustrated by people laughing at me	☐	☐	☐	☐	☐
15. I was worried by people's undue interest in me	☐	☐	☐	☐	☐
16. It was hard to stop thinking about people talking about me behind my back	☐	☐	☐	☐	☐
17. Certain individuals have had it in for me	☐	☐	☐	☐	☐
18. I have definitely been persecuted	☐	☐	☐	☐	☐

19. People have intended me harm	☐	☐	☐	☐	☐
20. People wanted me to feel threatened, so they stared at me	☐	☐	☐	☐	☐
21. I was sure certain people did things in order to annoy me	☐	☐	☐	☐	☐
22. I was convinced there was a conspiracy against me	☐	☐	☐	☐	☐
23. I was sure someone wanted to hurt me	☐	☐	☐	☐	☐
24. I was distressed by people wanting to harm me in some way	☐	☐	☐	☐	☐
25. I was preoccupied with thoughts of people trying to upset me deliberately	☐	☐	☐	☐	☐
26. I couldn't stop thinking about people wanting to confuse me	☐	☐	☐	☐	☐
27. I was distressed by being persecuted	☐	☐	☐	☐	☐

28. I was annoyed because others wanted to deliberately upset me	☐	☐	☐	☐	☐
29. The thought that people were persecuting me played on my mind	☐	☐	☐	☐	☐
30. It was difficult to stop thinking about people wanting to make me feel bad	☐	☐	☐	☐	☐
31. People have been hostile towards me on purpose	☐	☐	☐	☐	☐
32. I was angry that someone wanted to hurt me	☐	☐	☐	☐	☐

Page 8: PHQ-8

Over the last 2 weeks, how often have you been bothered by any of the following?

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐	☐	☐	☐
2. Feeling down, depressed, or hopeless	☐	☐	☐	☐
3. Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
4. Feeling tired or having little energy	☐	☐	☐	☐
5. Poor appetite or overeating	☐	☐	☐	☐
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
7. Trouble concentrating on things, such as reading the newspaper or watching television	☐	☐	☐	☐
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	☐	☐	☐	☐

PHQ-8 (Version 1, date: 1/6/2015)

Page 9: GAD-7

Over the past 2 weeks, how often have you been bothered by the following?

	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	☐	☐	☐	☐
2. Not being able to stop or control worrying	☐	☐	☐	☐
3. Worrying too much about different things	☐	☐	☐	☐
4. Trouble relaxing	☐	☐	☐	☐
5. Being so restless that it is hard to sit still	☐	☐	☐	☐
6. Becoming easily annoyed or irritable	☐	☐	☐	☐
7. Feeling afraid as if something awful might happen	☐	☐	☐	☐

GAD-7 (Version 1, date: 1/6/2015)

Page 10: UCLAL-20

The following statements describe how people sometimes feel. For each statement, please indicate how often you feel the way described.

	Never	Rarely	Sometimes	Always
1. How often do you feel you are "in tune" with the people around you?	☐	☐	☐	☐
2. How often do you feel you lack companionship?	☐	☐	☐	☐
3. How often do you feel there is no one you can turn to?	☐	☐	☐	☐
4. How often do you feel alone?	☐	☐	☐	☐
5. How often do you feel part of a group of friends?	☐	☐	☐	☐
6. How often do you feel you have a lot in common with the people around you?	☐	☐	☐	☐
7. How often do you feel you are no longer close to anyone?	☐	☐	☐	☐
8. How often do you feel your interests and ideas are not shared by those around you?	☐	☐	☐	☐
9. How often do you feel outgoing and friendly?	☐	☐	☐	☐
10. How often do you feel close to people?	☐	☐	☐	☐
11. How often do you feel left out?	☐	☐	☐	☐
12. How often do you feel your relationships with others are not meaningful?	☐	☐	☐	☐
13. How often do you feel no one really knows you well?	☐	☐	☐	☐

14. How often do you feel isolated from others?	☐	☐	☐	☐
15. How often do you feel you can find companionship when you want it?	☐	☐	☐	☐
16. How often do you feel there are people who really understand you?	☐	☐	☐	☐
17. How often do you feel shy?	☐	☐	☐	☐
18. How often do you feel people are around you but not with you?	☐	☐	☐	☐
19. How often do you feel there are people you can talk to?	☐	☐	☐	☐
20. How often do you feel there are people you can turn to?	☐	☐	☐	☐

UCLAL-20 (Version 1, date: 1/6/2015)

Page 11: CONTACT DETAILS

If you are selected for the virtual reality study or if you are the winner of one of four £25 Amazon vouchers, we will contact you by email. If you are willing to provide your telephone number, we may also contact you by telephone.

What is your email address?

What is your name? *Optional*

What is your telephone number? *Optional*

How did you find out about this study?

- Twitter
- Facebook
- Other online social network (not Twitter/Facebook)
- Messaging/chat service (e.g. SMS, WhatsApp)

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- Website
- Email
- Online advert
- Online forum
- Poster/flyer
- Verbally informed
- Other
- Prefer not to say

Page 12: END OF SURVEY

Thank you very much for completing this survey

You will now be entered into a prize draw to win one of four £25 Amazon vouchers, and for the chance to come to the Institute of Psychiatry, Psychology & Neuroscience (Denmark Hill, South East London) to take part in a virtual reality study.

We will get in touch if you are one of the successful winners of the Amazon vouchers or if we would like to invite you to take part in the virtual reality study. If you are invited for the virtual reality, you will be sent another information sheet and consent form. At this point you can decide if you wish to take part in the virtual reality study.

If this survey has raised any difficult thoughts or feelings for you and you wish to discuss them further, we would advise that you contact your GP or your local NHS IAPT (Improving Access to Psychological Therapies) service. If you wish to speak to someone immediately about these thoughts or feelings, you can contact the Samaritans on 08457 90 90 90 * (UK) or 116 123 (ROI).

Save or print this page if you wish to keep a copy for your records.

If you have any questions, please contact Dr Simon Riches or Dr Lucia Valmaggia:

Dr Simon Riches

King's College London

Institute of Psychiatry, Psychology & Neuroscience (PO78)

De Crespigny Park, Denmark Hill

London SE5 8AF, UK

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Dr Lucia Valmaggia

Scientific Advisor Virtual Reality Lab

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London SE5 8AF, UK

Lucia.valmaggia@kcl.ac.uk

Appendix V Study 2 recruitment tools

Sample recruitment email text

Subject: Virtual Reality study: Invitation to IoPPN [Participant number: *]**

Dear [Name/email],

Thank you very much for entering the Virtual Reality and Social Situations study and completing Stage 1 (online survey).

We would like to invite you for Stage 2 (Virtual Reality) at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London, De Crespigny Park, Denmark Hill, London SE5 8AF.

This part of the study will involve piloting a new Virtual Reality (VR) platform and aims to understand how people respond when entering a social environment in virtual reality. If you choose to accept this invitation, **you will be paid £10 for approximately 1 hour of your time**. I attach an Information Sheet and Consent Form for Stage 2 of the study. Please read the Information Sheet and decide if you would like to take part in the VR study.

Booking your VR Appointment
We use the Internet calendar tool Doodle to schedule appointments. This means that you can book yourself in for an appointment that is most convenient to you. In order to book your appointment, you will need the unique, 3 digit participant number that has been assigned to you.

Your participant number is: [Insert number]

Click the links below to book your appointment. Simply enter your unique 3-digit participant number in your chosen timeslot (where it says 'your name'). You do not need to enter any other information. We currently have appointment times on the following dates:

[Insert dates and time periods]
[Insert Doodle poll links]

Expand the poll if needed to see all appointment times. Please reserve just one appointment. If you book, change or cancel an appointment less than 24 hours before the appointment is due to take place, I would be very grateful if you could email me in addition to amending the Doodle.

On your VR Appointment Day
If your appointment is between 10am and 4pm on a weekday, please come to reception of the Henry Wellcome Building (reception phone no: 020 7848 0033). If your appointment is 4pm or afterwards on a weekday or is on the weekend, please come to reception of the Institute of Psychiatry, Psychology and Neuroscience: Main Building, 16 De Crespigny Park, SE5 8AF London (reception phone no: 020 7848 0002). These two building are next to each other. You will be met by a member of the research team.

Please find a map of the IoPPN Denmark Hill Campus here:

https://www.kcl.ac.uk/campuslife/campuses/download/2013/IoP-detail-map.pdf

Travel advice for getting to IoPPN can be found here:

http://www.kcl.ac.uk/ioppn/about/findus/index.aspx

Please bring a signed copy of the consent form if it is convenient for you. If this is not possible, blank copies will be available on the day.

Please do not consume any alcohol or drugs for at least 8 hours before your appointment.

If you do not wish to participate in Stage 2 (VR) or are unable to attend
I would be very grateful if you would let me know this as soon as possible. If I do not hear from you within 2 weeks, I will assume that you do not wish to participate in Stage 2.

Many thanks. We look forward to seeing you at the IoPPN.

Kind regards,
Simon Riches

Appendix VI Study 2 information sheet and consent form

Participant Information Sheet 2
(Virtual Reality)

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

We would like to invite you to participate in this original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Thank you for completing the online survey on thoughts and feelings about social situations. We would now like to invite you to take part in a virtual reality study being conducted for a doctoral degree at the Institute of Psychiatry, Psychology & Neuroscience, King's College London.

Research Aims

The study is aiming to pilot and test the feasibility of a new virtual reality platform and to understand people's thoughts and feelings when entering a social environment in virtual reality. The results of the study will inform the future development of a novel and effective assessment and treatment approach to help individuals with serious mental health problems facing difficulties with social situations.

What will happen to me if I take part?

If you decide to take part in the virtual reality study, you will be invited to the Institute of Psychiatry, Psychology & Neuroscience, King's College London, for an appointment at your convenience. This appointment will take about an hour. At the appointment you will be interviewed by a researcher and asked to fill out some online questionnaires for about 20 minutes. These questions will ask you about your thoughts and feelings, especially about social situations. Instruction in the use of the virtual reality equipment will then be given to ensure you feel comfortable with the equipment. Subsequently you will be asked to enter a 'virtual' social situation for a few minutes. In the virtual reality, you will enter a social situation, in which computer-controlled avatars will be present. You will be asked to carry out some brief tasks. We will also ask you to wear a small heart monitor on your finger. You will then be asked about your experience of the virtual environment and to complete some questionnaires. If you are willing, some of your responses will be audio-recorded. These recordings will be destroyed at the end of the study.

Study Outcomes

The results of the study are unlikely to be published before 2016. Copies of the published results will be available to you on request.

Confidentiality

Your responses will be confidential. All data is stored in a password protected electronic format. The results of this study will be used for academic publications and presentations but all data will be anonymised.

Your Right to Withdraw

You are free to withdraw from this study at any time, without giving a reason. If you decide to take part, you will be asked to sign a consent form. If after taking part you decide that you would no longer like your audio recording to be used, you are entitled to ask for your interview

tape to be destroyed and/or your data to be removed from the project, until it is no longer practical to do so (e.g. once the final report is written). Partially completed questionnaires will not be used.

Disadvantages or Risks
When people use virtual reality systems, some people sometimes experience some degree of nausea. If at any time you wish to stop taking part in the study due to this or any other reason, please just say so and we will stop immediately. There has been some research that suggests that people using head-mounted displays might experience some disturbances in vision afterwards. No long term studies are known to us, but the studies which have been carried out do testing after about 30 minutes, and find the effect is still sometimes there. It is advised that participants do not drive a car, motorcycle, or use any piece of complicated machinery in the four hours immediately following being in virtual reality. There have been various reported side effects of using virtual reality equipment, such as 'flashbacks'. There is a possibility that an epileptic episode may be generated by the virtual reality equipment. This, for example, has been reported for computer video games. If you have a history of epilepsy we would not want you to take part in the study.

Ethical Approval
This study has been approved by the Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London.

Contact
If you want more information on this study or if this study has harmed you in any way, please contact:

Dr Simon Riches
King's College London
PO78, Institute of Psychiatry, Psychology & Neuroscience
De Crespigny Park, Denmark Hill
London, SE5 8AF
simon.s.riches@kcl.ac.uk

Dr Lucia Valmaggia
Scientific Advisor Virtual Reality Lab
King's College London
Institute of Psychiatry, Psychology and Neuroscience
Department of Psychology (PO 77)
De Crespigny Park | LONDON | SE5 8AF | UK
Lucia.valmaggia@kcl.ac.uk

Thank you for considering taking part in this study.

Consent Form 2
(Virtual Reality)

KING'S College LONDON

VIRTUAL REALITY AND
SOCIAL SITUATIONS STUDY

PARTICIPANT NUMBER: ☐

Participant's Statement: Please initial box

1. I confirm that I have read and understand the Information Sheet, dated 10/8/2015 (Version 2), for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that the research data collected during the study will be looked at by members of the research team. ☐
4. I am willing for part of the post-VR interview to be digitally recorded. ☐
5. I agree to take part in the above study. ☐

----------	----------	----------
Name	Date	Signature

Researcher's statement:
I confirm that the study has been explained to the participant and that any questions have been answered.

----------	----------	----------
Name	Date	Signature

Appendix VII Instruction manual for VR data collection procedure

VR DATA COLLECTION
INSTRUCTION MANUAL

DO NOT TAKE AWAY

VR DATA COLLECTION EQUIPMENT

Ring Binder 1 (Blank Forms)

Information Sheets

Consent Forms

Semi-structured interview form

Paranoia leaflet

Payment Claim Form

Confirmation of Participation Form

Ring Binder 2 (Completed Participant Packs)

Signed Consent Forms

Completed semi-structured interview forms

Completed payment claim forms

Completed confirmation of participation forms

Stationary

Pens

Clipboard

Clear plastic envelopes

Electronic Equipment

Tablet 1

Tablet 2

VR headset (plus eye glass cleaner)

Desktop computer

Oximeter

Dictaphone

VR DATA COLLECTION ITINERARY AND RESEARCH EQUIPMENT FOR ONE PARTICIPANT

TIME POINT	BEFORE: YOU WILL NEED	KEY TASK	AFTER: YOU SHOULD HAVE	LAB	RESEARCHER
T1	• Information Sheet • Consent Form • Tablet 1	• Meet participant in reception (Main Building or HWB) • Brief participant • Discuss Information Sheet • Sign Consent Form • Pre-VR survey (on tablet) • Take participant to holding area	• Signed Consent Form	2.22, HWB (Interview Room)	R1
T2	• VR headset • Desktop computer • Oximeter • Tablet 2	• Collect participant from holding area • Brief participant • Oximeter reading 1 • VR task • Oximeter reading 2 • Post-VR survey (on tablet) • Take participant to holding area		2.21, HWB (VR Lab)	R2
T3	• Semi-structured interview form • Dictaphone • Paranoia leaflet • Payment Claim Form • Confirmation of Participation Form	• Collect participant from holding area • Post-VR interview (5 minutes, audio recorded) • Debrief – any questions? • Explain what the study is about • Offer paranoia leaflet (if needed) • Complete payment claim form • Complete confirmation of participation form • See participant out of building	• Completed semi-structured interview form • Completed payment claim form • Completed confirmation of participation form *****RESEARCHER NOW PUTS THE ABOVE 4 DOCUMENTS TOGETHER INTO A CLEAR ENVELOPE AND FILES THEM IN RING BINDER 2*****	2.22, HWB Interview Room)	R1

HWB = Henry Wellcome Building

VR DATA COLLECTION INSTRUCTIONS FOR ONE PARTICIPANT

PART 1

R1. Meet participant in reception of HWB or main building. Bring them up to Interview room.

R1. *Interview room*

- **Briefing:** *Sample script: "Thank you for coming to do the virtual reality study today. You were sent an Information Sheet. Did you read the Information Sheet?* [If yes:] *Did you have any questions?* [Use information sheet as prompt and answer questions.] [If no:] *Would you like to have a quick read of it now? Take your time … Did you have any questions?* [If participant would like a summary, key points in brief are:] *"The purpose of today is to do a virtual reality task and ask you a few questions before and after about how you found the experience. The virtual reality scenario is a social situation. All of the information that we collect today is completely confidential. You are free to stop the study or take a break at any time."* [If the participant asks any questions about the design of the study or how they were selected:] *"I'm afraid I can't answer that question before you do the virtual reality task but there will be a debriefing afterwards where I will be able to answer any questions."*
- **Consent form:** Sign or collect signed copy. Researcher to sign and retain 1 copy. Make sure participant has completed all sections correctly before you sign. Ask participant if they would also like a copy for their records and, if so, complete a second consent form.
- **Questions on tablet:** *Sample script: "We would just like to ask you a few questions before you do the virtual reality task. We have the questions on this tablet. They are similar to the questions you answered in the online survey. Let me know if you have any questions …"* [If participant finds question formatting on tablet difficult:] *"You may find it easier to switch to 'tableless mode'."*
- **End:** *Sample script: "It is now time to do the virtual reality task with my colleague. I will take you through to them"*

R1 to stay with participant in holding area until R2 is ready to collect them

PART 2

On screen: VR PARTICIPANT > RUN (Loading). VR headset must be facing the screen while scenario is loading.

R2. *VR lab*

- **Introduction:** *Sample script: "This is the part of the study where we will do the virtual reality task"*
- **Oximeter reading 1:** *Sample script: "First of all, we would just like to take reading of your heart rate using this device that goes on your finger. It does not hurt at all."* Demonstrate putting on the oximeter. *"We will take another reading of your heart rate after you've done the virtual reality task"*. [Enter Oximeter reading 1 on tablet. Top figure is blood oxygen, bottom figure is heart rate – if blood oxygen is less than 90, contact Lucia.]
- **Explain VR equipment**: Before putting on the headset, show the participant the Oculus headset and the joypad. Show them which button on the joypad they will be able to use. Tell the participant: *"You will be able to move around with a combination of turning with your body and by using the joypad. Move around slowly at first as you get used to the virtual environment; otherwise you might feel dizzy. If you've used a joypad before, it might be a bit different to what you are used to as you will be partially guided in your movement and cannot move completely freely"* Demonstrate this to participant while holding the joypad.
- **Start VR:** Get participant into position, holding joypad and wearing VR headset. Make sure headset cable is not tangled. Sample script: *"Don't worry about the cable. I will make sure you do not get tangled."* Blue light on headset must be on. Once the participant is comfortable and ready, press PLAY.
- **Demo VR exercise:** [Now read the following:] "*You will first be in a street. Have a look around the street slowly … When you are ready, use the joypad to move yourself to the green circle on the ground … You will get to a pub. Turn your body to the right to face the pub … In the pub look for more green circles on the ground. You will need to go from one green circle to another. If you cannot find a green circle, have a look around for it. When you get to a green circle, you will need to stop for a little while. <u>While you are in the pub please try get an impression of what the people in the pub thinks about you and what you think about them. If someone asks you a question, try to reply to them</u>"* [Everyone <u>MUST</u> get this instruction.] *"Do you have any questions?"*
- **Main VR task:**

Press PLAY at pub doorway

'PAUSE' > CONTINUE

AFTER PATRICK > CONTINUE

2ND INTERACTION > WALK AROUND

AFTER TV PROGRAMME > CONTINUE

CLOSING INSTRUCTION > CONTINUE

- **FIDELITY:** Record on tablet. DO NOT SPEAK TO PARTICIPANT WHILE IN THE PUB UNLESS NECESSARY.
- **Oximeter reading 2:** As soon as VR task ends, while participant is still wearing VR headset, take another heart reading. *Sample script: "We would just like to take another reading of your heart rate using the same device as before"*

- **Remove VR equipment**
- **Questions on tablet:** *"Now that you've done the virtual reality task, we would just like to ask you a few more questions on this tablet.* … [If participant finds question formatting on tablet difficult:] *You may find it easier to switch to 'tableless mode'.*
- **End:** *Sample script: "Thank you for doing the virtual reality task. I am just going to take you back to my colleague who has a few more questions for you and can answer any questions you might have"*

R2 to stay with participant in holding area until R1 is ready to collect them

PART 3

R1. *Interview room*

- **Post-VR semi-structured interview:** See form for script.
- **General debrief:** *Sample script: "Now that you've completed the main parts of the study, I wanted to give you a little more information about the research. It's also an opportunity for you to ask any further questions. This study is looking at the various emotional responses that people have in a virtual reality social situation. In particular, we are looking at how the virtual reality scenario of a social situation affects peoples' experience of paranoia. In order to do this we selected some participants of higher paranoia and some participant of lower paranoia, based on their answers on the online survey, to come and do the virtual reality task* [Pause for any questions] *Given that all participant data is anonymised, we do not know which participants that do the virtual reality are higher or lower. Do you have a*ny *questions about study?*
- **[Optional] Normalise paranoia:** [If participant has any concerns about their paranoia, normalise paranoia in the general population:] *"Paranoia is very common. Everyone experiences some degree of paranoia."*
- **[Optional] Paranoia leaflet/signpost to GP:** [If participant has further concerns about their paranoia, give them the paranoia leaflet. If participant has still further concerns and feels they need to discuss this with someone, signpost them to contacting their GP:] *Sample script: "If you feel that this has raised any difficult thoughts or feelings for you and that you would like to discuss them further with someone, we would suggest that you discuss this with your GP."*
- **[Optional] Results of study:** [If participants would like to know about the results of the study:] *Sample script: "We will be happy to send you the final report when it is completed. We can have it emailed to you"* [Record on tablet that participant would like published report/paper emailed to them].
- **Keeping debrief confidential:** *Sample script: "If you happen to know other participants in the virtual reality study, we would be very grateful if you do not share this explanation with them until the virtual reality data collection is completed."*
- **Payment:** Fill out details for bank transfer or cheque payment
- **Participation confirmation:** Complete Confirmation of participation form
- **End:** *Sample script: "Thank you very much for coming today. I will show you out"*

See participant out of building

VR DATA COLLECTION SCHEDULE

Times

Thursday day = 09.20-18.00 (11 slots)
Friday day = 09.20-17.40 (10 slots)
Monday evening = 17.20-21.20 (6 slots)
Wednesday evening = 18.20-22.00 (6 slots)
Saturday afternoon = 14.00-18.00 (6 slots)

Researchers to meet half an hour before to set up.

R1 to speak to relevant receptionist about format of day, explain where study is taking place, and tell receptionist to ask participants to take a seat in reception and that they will be collected by a researcher.

R1 to fix "Do not disturb. Data collection in progress" signs on doors of both labs.

Dates

Week	Date	Year	Time period	Researchers	Time slots
1	Fri 11 Dec		Team Meeting	SR, CE, NS, KY	0
	Fri 11 Dec		Afternoon	SR, CE, NS, KY	6
	Sat 12 Dec		Afternoon	SR, NS	6
2	Mon 14 Dec		Evening	SR, KY	6
	Wed 16 Dec		Evening	CE, NS	6
	Thurs 17 Dec		Day	CE, NS	11
	Fri 18 Dec		Team Meeting	SR, CE, NS, KY	0
	Fri 18 Dec		Day	SR, KY	10
3	Mon 21 Dec		Day	SR, KY	11
4	Thurs 7 Jan	2016	Day	CE, NS	11
	Fri 8 Jan		Team Meeting	SR, CE, NS, KY	0
	Fri 8 Jan		Day	SR, KY	10
5	Mon 11 Jan		Morning	SR	?
	Thurs 14 Jan		Day	CE, NS	11
	Fri 15 Jan		Team Meeting	SR, CE, NS, KY	0
	Fri 15 Jan		Day	SR, KY	10
6	Thurs 21 Jan		Day	CE, NS	11
	Fri 22 Jan		Team Meeting	SR, CE, NS, KY	0
	Fri 22 Jan		Day	SR, KY	10
7	Mon 25 Jan		Day	SR	?
	Thurs 28 Jan		Day	CE, NS	11
	Fri 29 Jan		Team Meeting	SR, CE, NS, KY	0
	Fri 29 Jan		Day	SR, KY	10

Total: 140

THURSDAY/FRIDAY DAYS & WEDNESDAY EVENINGS

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P16	P17
09.20	T1																
09.40	T2	T1															
10.00	T3	T2															
10.20		T3															
10.40			T1														
11.00			T2	T1													
11.20			T3	T2													
11.40				T3													
12.00					T1												
12.20					T2	T1											
12.40					T3	T2											
13.00						T3											
13.20																	
13.40	BREAK																
14.00																	
14.20							T1										
14.40							T2	T1									
15.00							T3	T2									
15.20								T3									
15.40									T1								
16.00									T2	T1							
16.20									T3	T2							
16.40										T3							
17.00											T1						
17.20											T2						
17.40											T3						
18.00	BREAK																
18.20												T1					
18.40												T2	T1				
19.00												T3	T2				
19.20													T3				
19.40														T1			
20.00														T2	T1		
20.20														T3	T2		
20.40															T3		
21.00																T1	
21.20																T2	T1
21.40																T3	T2
22.00																	T3

ALTERNATIVE FRIDAY DAYS

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
09.20	T1									
09.40	T2	T1								
10.00	T3	T2								
10.20		T3								
10.40			T1							
11.00			T2	T1						
11.20			T3	T2						
11.40				T3						
12.00	BREAK									
12.20										
12.40	TEAM MEETING									
13.00										
13.20										
13.40					T1					
14.00					T2	T1				
14.20					T3	T2				
14.40						T3				
15.00							T1			
15.20							T2	T1		
15.40							T3	T2		
16.00								T3		
16.20									T1	
16.40									T2	T1
17.00									T3	T2
17.20										T3

SATURDAY AFTERNOONS

	P1	P2	P3	P4	P5	P6
14.00	T1					
14.20	T2	T1				
14.40	T3	T2				
15.00		T3				
15.20			T1			
15.40			T2	T1		
16.00			T3	T2		
16.20				T3		
16.40					T1	
17.00					T2	T1
17.20					T3	T2
17.40						T3

MONDAY EVENINGS

	P1	P2	P3	P4	P5	P6
17.20	T1					
17.40	T2	T1				
18.00	T3	T2				
18.20		T3				
18.40			T1			
19.00			T2	T1		
19.20			T3	T2		
19.40				T3		
20.00					T1	
20.20					T2	T1
20.40					T3	T2
21.00						T3

Appendix VIII Information for IoPPN receptionists

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

- We are doing the Virtual Reality and Social Situations study at the IoPPN today

- Participants will be reporting to reception

- Participants may ask for Simon Riches or Lucia Valmaggia or say that they are here for the Virtual Reality study

- Please ask them to take a seat in reception

- A researcher will come to collect them

Appendix IX Pre-VR measures BOS output

PRE-VR QUESTIONS

Page 1: WELCOME

Participant number:

Researcher initials:

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

Pre-VR Questions

You have been invited to experience a brief social situation in a virtual reality. Before we ask you to enter the virtual reality, we would like to ask you a few questions about your thoughts and feelings. If you have any questions the researchers will be available to assist throughout the process.

Introduction Sheet (Pre-VR) (Version 1, date: 1/6/2015)

Page 2: PHQ-8

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐	☐	☐	☐
2. Feeling down, depressed, or hopeless	☐	☐	☐	☐
3. Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
4. Feeling tired or having little energy	☐	☐	☐	☐
5. Poor appetite or overeating	☐	☐	☐	☐
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
7. Trouble concentrating on things, such as reading the newspaper or watching television	☐	☐	☐	☐
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	☐	☐	☐	☐

PHQ-8 (Version 1, date: 1/6/2015)

Page 3: GAD-7

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	☐	☐	☐	☐
2. Not being able to stop or control worrying	☐	☐	☐	☐
3. Worrying too much about different things	☐	☐	☐	☐
4. Trouble relaxing	☐	☐	☐	☐
5. Being so restless that it is hard to sit still	☐	☐	☐	☐
6. Becoming easily annoyed or irritable	☐	☐	☐	☐
7. Feeling afraid as if something awful might happen	☐	☐	☐	☐

GAD-7 (Version 1, date: 1/6/2015)

Page 4: SPM-6

For the following statements, please rate how you feel "right now" from 1 ("not at all") to 10 ("totally")

	1	2	3	4	5	6	7	8	9	10
1. There is a conspiracy against me	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. I am being deliberately harmed or upset	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. I am being followed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. I am being persecuted	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. I am feeling under threat from others	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. I am being laughed at behind my back	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

SPM-6 (Version 1, date: 1/6/2015)

Page 5: VAS Pre-VR-4

For the following questions, please rate how you feel "right now" from 1 ("not at all") to 10 ("extremely")

	1	2	3	4	5	6	7	8	9	10
1. How stressed do you feel right now?										
2. How anxious do you feel right now?										
3. How miserable or sad do you feel right now?										
4. How happy do you feel right now?										

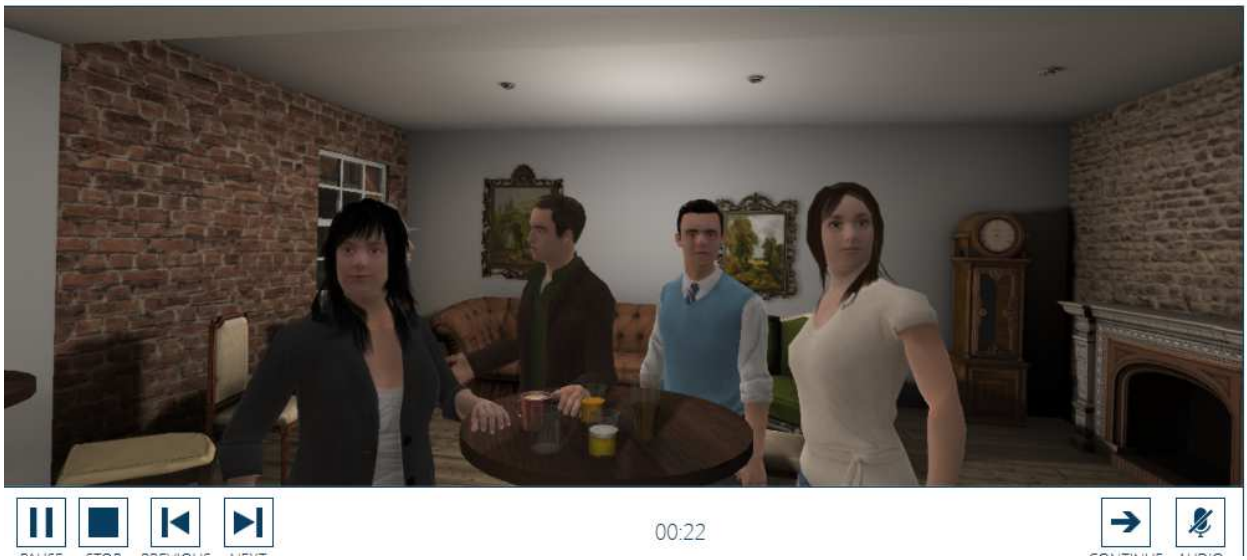
VAS Pre-VR-4 (Version 1, date: 1/6/2015)

Page 6: End of survey

Thank you for answering these questions. You will now be taken to do the virtual reality task.

Appendix X VR scenario stills


Designed by Virtualware for King's College London


00:22

Appendix XI VR fidelity and heart rate measures BOS output

KING'S College LONDON

University of London

OXIMETER & VR PROCEDURE

Page 1

1 Participant number:

2 Researcher initials:

3 Oximeter 1:

4 Did the participant complete the VR task?

- Completed task
- Partially completed task
- Did not do task

5 Did you speak to the participant while they were in the pub?

- Yes
- No

6 Oximeter 2:

Page 2: Thanks

Appendix XII Post-VR measures BOS output

KING'S College LONDON
University of London

POST-VR QUESTIONS

Page 1: WELCOME BACK

Participant number:

Researcher initials:

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY

Post-VR Questions

Thank you for taking part in the virtual reality task. We would be very grateful if you could answer a few questions about your experience. Some of the questions will be general questions about your thoughts and feelings and others will be specific to how you felt in the virtual reality 'social situation'.

Introduction Sheet (Post-VR) (Version 1, date: 1/6/2015)

Page 2: VAS Post-VR-15

For the following questions, please rate how you feel “right now” from 1 ("not at all") to 10 ("extremely")

	1	2	3	4	5	6	7	8	9	10
1. How stressed do you feel?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. How anxious do you feel?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. How miserable or sad do you feel?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. How happy do you feel?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

For the following questions, please rate how you felt in the social situation from 1 ("not at all") to 10 ("extremely")

	1	2	3	4	5	6	7	8	9	10
5. How paranoid did you feel?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. How friendly did you find the people?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. How neutral did you find the people?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8. How hostile did you find the people?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9. How socially anxious did you feel with the people?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10. How much did you want to avoid social interaction with others?	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐
11. Were you that afraid other people would not approve of you?	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐
12. Were you worried that you would say or do the wrong thing?	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐

13. How positively or negatively did you think the other people were thinking during the social situation?

	1	2	3	4	5	6	7	8	9	10
Please rate from 1 ("very negatively") to 10 ("very positively")	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐	⌐

14. Please state which was strongest on the whole, your sense of being in the real world of the laboratory or your sense of being in the virtual social situation?

	1	2	3	4	5	6	7	8	9	10

Please rate from 1 ("being in the laboratory") to 10 ("being in the virtual social situation")	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

15. How much did you enjoy the virtual reality experience?

	1	2	3	4	5	6	7	8	9	10
Please rate from 1 ("did not enjoy it") to 10 ("enjoyed it very much")	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

VAS Post-VR-15 (Version 1, date: 1/6/2015)

Page 3: SSPS-20

We are interested in your views of the other people who were in the social situation. Please circle how much you agree or disagree with the following statements based upon your thoughts when you were in the social situation

	Do not agree	Agree a little	Agree moderately	Agree very much	Totally agree
1. Someone was hostile towards me	☐	☐	☐	☐	☐
2. No-one had any particular feelings about me	☐	☐	☐	☐	☐
3. Someone had bad intentions towards me	☐	☐	☐	☐	☐
4. Someone was friendly towards me	☐	☐	☐	☐	☐
5. Someone was trying to make me distressed	☐	☐	☐	☐	☐
6. I felt very safe in their company	☐	☐	☐	☐	☐
7. Someone stared at me in order to upset me	☐	☐	☐	☐	☐
8. Everyone was trustworthy	☐	☐	☐	☐	☐
9. Someone wanted me to feel threatened	☐	☐	☐	☐	☐
10. I wasn't really noticed by anybody	☐	☐	☐	☐	☐
11. Someone had kind intentions toward me	☐	☐	☐	☐	☐
12. Someone would have harmed me in some way if they could	☐	☐	☐	☐	☐
13. Someone had it in for me	☐	☐	☐	☐	☐
14. Everyone was neutral towards me	☐	☐	☐	☐	☐
15. Someone was trying to intimidate me	☐	☐	☐	☐	☐
16. Everyone was pleasant	☐	☐	☐	☐	☐

17. Someone was trying to isolate me	⌐	⌐	⌐	⌐	⌐
18. No-one had any intentions towards me	⌐	⌐	⌐	⌐	⌐
19. Everyone seemed unconcerned by my presence	⌐	⌐	⌐	⌐	⌐
20. Someone was trying to irritate me	⌐	⌐	⌐	⌐	⌐

SSPS-20 (Version 1, date: 1/6/2015)

Page 4: SPM-6

For the following statements, please rate how you feel “right now” from 1 ("not at all") to 10 ("totally")

	1	2	3	4	5	6	7	8	9	10
1. I am being deliberately harmed or upset	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. There is a conspiracy against me	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. I am being followed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. I am being persecuted	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. I am feeling under threat from others	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. I am being laughed at behind my back	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

SPM-6 (Version 1, date: 1/6/2015)

Page 5: SUS-6

1. Please rate your sense of being in the virtual environment, on a scale of 1 to 7, where 7 represents your normal experience of being in a place

	1 ("Not at all")	2	3	4	5	6	7 ("Very much")
"I had a sense of "being there" in the social situation..."	☐	☐	☐	☐	☐	☐	☐

2. To what extent were there times during the experience when the social situation was the reality for you?

	1 ("At no time...")	2	3	4	5	6	7 ("Almost all the time")
"There were times during the experience when the social situation was the reality for me..."	☐	☐	☐	☐	☐	☐	☐

3. When you think back to the experience, do you think of the social situation more as images that you saw or more as somewhere that you visited?

	1 ("Images that I saw")	2	3	4	5	6	7 ("Somewhere that I visited")
"The social situation seems to me to be more like... "	☐	☐	☐	☐	☐	☐	☐

4. During the time of the experience, which was the strongest on the whole, your sense of being in the social situation or of being elsewhere?

	1 ("Being elsewhere")	2	3	4	5	6	7 ("Being in the social situation")
"I had a stronger sense of... "	☐	☐	☐	☐	☐	☐	☐

5. Consider your memory of being in the social situation. How similar in terms of the structure of the memory is this to the structure of the memory of other places you have been today? By 'structure of the memory' consider things like the extent to which you have a visual memory of the social situation, whether that memory is in colour, the extent to which the memory seems vivid or realistic, its size, location in your imagination, the extent to which it is panoramic in your imagination, and other such structural elements.

	1 ("Not at all")	2	3	4	5	6	7 ("Very much so")
"I think of the social situation as a situation in a way similar to other situations that I've been in today..."	☐	☐	☐	☐	☐	☐	☐

6. During the time of your experience, did you often think to yourself that you were actually in the social situation?

	1 ("Not very often")	2	3	4	5	6	7 ("Very much so")
"During the experience I often thought that I was really in the social situation... "	☐	☐	☐	☐	☐	☐	☐

SUS-6 (Version1, date: 1/6/2015)

Page 6: General

Have you used virtual reality before?

- Yes
- No

Do you play computer games regularly?

- Yes
- No

Page 7: End of survey

Thank you very much for answering these questions

Appendix XIII Post-VR interview

PARTICIPANT NUMBER: **DATE:**

RESEARCHER:

Post VR Interview – Version 1, 1/6/2015

"We would now like to ask you a few questions about your experience in the VR today. These are questions we ask everyone. It will take about 5 minutes. I am going to switch on the voice recorder, OK?"

Once recording speak clearly in the microphone quoting **the person's participant number and today's date: "This is participant [PARTICIPANT NUMBER] and the date is [DATE]"**. Then probe for Information about the individual experience of the social situation by asking the following questions:

1) "What did you think about your virtual reality experience?"

2) "What thoughts ran through your mind while you were the social situation (don't worry about how trivial they seem, I am just interested in the sort of thoughts that popped into your head in the few minutes you were there). What did you think of the people in the social situation? What did you think they thought about you?"

3) "What made you think that? [i.e. on what evidence did they base their thoughts] (e.g. was it something about how you were feeling? Or was it something specific that the people did?)"

4) "Do you think the people in the social situation had any intentions towards you?"

5) "How are you feeling now? Did you feel emotional in any way while you were in the social situation?"

6) "Do you go out socially? Do you go to pubs or bars? How did you think the virtual social situation compared to your experience of being in real social situations?"

7) "Do you have any other comments?"

"Thank you. I will now turn off the voice recorder"

Appendix XIV Paranoia leaflet

Institute of Psychiatry

South London and Maudsley NHS

wellcome trust

paranoid thoughts

Information about paranoid thoughts and paranoia

It sometimes seems as if the one thing that unites the diverse peoples of the world is our fear of one another. Worries about other people are so common that they seem to be an essential - if unwelcome - part of what it means to be human.

The focus of this website is not on justified anxieties about others, but rather on exaggerated or unfounded fears - fears for which there is little or no convincing evidence. Exaggerated worries about others don't help us stay safe but instead can bring all manner of distress.

What is paranoia?

We could have called this section: What are fears about others? We could also have titled it: What are paranoid feelings? Or: What are persecutory beliefs? Some people use the terms delusional thoughts or, for severe instances, persecutory delusions. The feelings discussed in this website, then, go by a variety of names. Partly this is because paranoia is a term that covers a wide spectrum of experiences. What we mean is:

- The fear of something bad happening
- The idea that others may intend to cause such an event>
- The thought is exagerrated or unfounded.

These fears normally contain certain elements: a perpetrator, a type of threat, and a reason. We can suspect absolutely anyone of wanting to do us harm. Often the perpetrator is a neighbour, stranger, work colleague or family member. Occasionally it may be government organisations or spirits. Sometimes the identity of the person trying to cause the harm is unknown. The type of harm varies too. But typically the fear is of physical, psychological, social or financial harm. Why do people think others are targeting them for harm? Sometimes there's a feeling of simply being a victim, sometimes it is suspected that we're at risk because of who we are, and sometimes it because we think the threat is provoked by something we've done.

How can we tell whether our suspicious thoughts are justified?

How can we tell whether our worries are justified or not? Well, it's not always easy. If you're struggling to decide whether your suspicious thoughts are justified, ask yourself the following questions:

1. Would other people think my suspicions are realistic?
2. What would my best friend say?
3. Have I talked to others about my worries?
4. Is it possible that I have exaggerated the threat?
5. Is there any indisputable evidence for my suspicions?
6. Are my worries based on ambiguous events?
7. Are my worries based on my feelings rather than indisputable evidence?
8. Is it very likely that I would be singled out above anyone else?
9. Is there any evidence that runs contrary to my suspicions?
10. Is it possible that I'm being at all over-sensitive?
11. Do my suspicions persist despite reassurance from others that they are unfounded?

There are no hard and fast rules for deciding for certain whether a worry is realistic. But by asking yourself these questions you can determine the probability of the suspicion being justified.

The probability that your fears are unrealistic increases the more you feel that:

- No one else fully shares your suspicions
- There is no indisputable evidence to support your worries
- There is evidence against your suspicions
- It is unlikely that you would be singled out
- Your fears persist despite reassurance from others
- Your fears are based on feelings and ambiguous events

What are the causes of paranoia?

"A lot of the time I feel someone. I have no idea who, is watching me. When I'm out in public, I always get the feeling that someone is either following me or is watching me. I really don't trust anyone but myself anymore."

Read more personal accounts of paranoia

Research has identified five main factors involved in the occurrence of suspicious thoughts. All five factors are very common - all of us will have experienced at least some of them. What's important though is the way they combine. Suspicious thoughts are caused by a combination of some or all of these five factors:

- Stress and major life changes. This includes difficult relationships with others at home or at work, and becoming isolated.
- Negative emotions such as anxiety and depression. Often when we are anxious we can overestimate the chances of threat and worry too much. The way we feel has a big influence on the way we think.
- Internal unusual feelings. Stress can often cause strange feelings (eg. feeling odd, aroused, threatened), as can going without sleep. Sometimes people can feel odd because they have taken drugs such as cannabis.
- Our explanations. Paranoid thoughts are our way of trying to understand things. They are attempts to make sense of events. It's perfectly natural to try to understand the world around us - and the way we feel inside. But when we're stressed and feeling low or anxious or irritable our explanations are likely to be pretty negative. We think the worst - and often we think the worst of people around us. It can seem as if the odd or unpleasant things we've been experiencing are deliberately caused by other people.
- Reasoning (the way we think things through and come to decisions and judgements). Often suspicious thoughts can take a grip if we do not think of alternative explanations for events, and do not fully consider the evidence for and against our worries. This is sometimes called jumping to conclusions.
- So, when we are stressed and things are perhaps not going too well, we can become anxious and interpret how we feel in terms of threat from other people, without fully weighing the evidence or considering alternative explanations.

How common is paranoia?

Until very recently - the last 15 to 20 years in fact - no one suspected just how many people had paranoid thoughts. But several research projects have now lifted the lid - and the results are striking. Here are just a few statistics from some of those research projects.

- In a survey of 8580 UK adults, 21% said there'd been times over the past year when they'd felt people were against them. 9% said they'd believed that their thoughts were being controlled or interfered with by some outside force or person. 1.5% said there'd been times when they'd felt people were plotting to cause them serious harm.
- A study of 1005 adults in New York found that 10.6% believed other people were following or spying on them. 6.9% thought people were plotting against them, or trying to poison them. 4.6% believed people were either secretly testing them, or experimenting upon them.
- A French survey of 462 adults found that 25% had, at some point in their lives, felt that they were being persecuted in some way. 10.4% had sometimes believed there was a conspiracy against them.
- A study of 1202 British university students (aged 16 to 61) assessed their feelings over the previous month. 42% said that, at least once a week, they had thought that negative comments about them might be circulating. 27% had felt that people were deliberately trying to irritate them, and 19% had thought that they might be being observed or followed. 5% thought there might be a conspiracy against them.
- More than a thousand older adults (aged 55 and above) in Brooklyn, New York were assessed. 13% had, in the previous week, experienced paranoid thoughts.
- Paranoia, then, is widespread - so widespread, in fact, that around 15 to 20% of the population have frequent paranoid thoughts. Most of those people aren't much troubled by their suspicious thoughts. But a further 3 to 5 % have pretty severe paranoia. For this smaller group of people, their paranoia is often serious enough to need specialist treatment.

Overcoming paranoia

Look after yourself. We're more likely to be troubled by paranoia if we're tired or run-down or very stressed. So make sure you eat healthily, get plenty of good-quality sleep, and exercise regularly. Make time too for things you enjoy: the more positive activities you have in your life, the less scope there'll be for paranoia to take hold.

Drinking too much, and using illicit drugs, can sometimes trigger paranoid thoughts. If you think they may be a factor in your paranoia, cut back or stop completely.

Consider the pros and cons. As we've seen, underlying paranoia is a fundamental decision about whether or not to trust other people. As a device to help you explore your own approach to this issue, make a list of the pros and cons of both trusting people and mistrusting them. Have you got the balance right, do you think? Would you like to be less mistrustful? Are there experiences from your past that might be having too great an influence on how you see people now

Share your fears. We know that people who don't talk about their paranoid thoughts generally find them more upsetting. So confide in someone you trust. Getting another perspective on your worries can be really helpful.

Get to know your paranoia. Like all problems, it's much easier to cope with our paranoid thoughts if we have a clear picture of them. So for the next seven days keep a diary of your paranoid thoughts - what they are, when they occur, and what might trigger them.

You may well find that particular situations tend to spark your paranoia (perhaps being very anxious or angry or bored, for example). And that will give you the chance to think how you can prevent these situations occurring, or at least how

to deal with them better.

Incidentally, one of the great benefits of keeping a diary is that it gets your paranoid thoughts out of your head and onto paper. For many people, that can be a huge relief, and a terrific way of putting some distance between themselves and their paranoia.

Manage your worry. Worry is a very common reaction to paranoid thoughts. People fret about the harm they think other people intend towards them, and sometimes they also worry about what having these thoughts might mean (for example, that they're going mad). But the more we worry, the more anxious and fearful we become. Worry feeds on worry.

So we need to learn to manage our worry. One very useful technique is to save up all your worrying for one half-hour session every day: your worry period. And instead of worrying, try focusing your energy on solving the problem that's troubling you.

Challenge your paranoid thoughts. Choose a suspicious thought from your paranoia diary, and weigh up the evidence for and against it. Ask yourself these questions:

- Is there anything that might suggest the thought is wrong?
- What would my family or friends say if I talked to them about the thought?
- What would I say to a friend who came to me with a similar problem?
- Are there any alternative explanations for what seems to have happened?
- Are my thoughts based more on the way I feel than on solid evidence?
- Have I been jumping to conclusions?
- If I were feeling happier or less anxious or less tired, would I still see things in the same way?

Test out your thoughts. Paranoia can make people so anxious and afraid that they change their behaviour, avoiding the situations that trigger their fears. But this only reinforces their paranoia, because it robs them of the chance to discover whether or not their fears are justified.

Testing out your paranoid thoughts involves actively seeking out the situations you're afraid of. That can be pretty nerve-wracking, so you need to go carefully. Draw up a list of tasks you find difficult and start with the relatively easy ones. Once you're comfortable with those, gradually work your way up to the more difficult tasks.

Incidentally, don't put yourself in situations where you're likely to be at real risk. You may be worried about going out alone, for instance, but don't test this by going into a dangerous neighbourhood at night. Concentrate on activities that most people would find reasonable and where you think your suspicious thoughts are probably exaggerated.

Let go of your paranoid thoughts. We're bound to have suspicious thoughts from time to time. It's unrealistic to think we can put a complete stop to them, but we can improve the way we deal with these thoughts when they do occur.

The trick is not to focus on them, to develop what's known as a mindful attitude. Don't fight your thoughts and don't spend time thinking about them. Try to be detached. Watch the thought come to you, remind yourself that it doesn't matter, and let it go off into the distance. Concentrate on what you're doing, rather than what you're thinking.

People often find it helps to repeat an encouraging phrase to themselves, for example "They're only thoughts - they don't matter"; "Keep going - you're doing really well"; "These thoughts don't scare me. I can cope."

Appendix XV Participant payment forms

KING'S College LONDON
University of London

EXPENSES CLAIM FOR KCL STAFF, STUDENTS AND NON-STAFF

1. This form must NOT be used to request payment for any kind of work performed. Please contact Payroll.
2. All sections must be completed clearly within the boxed indicated. Failure to do so may mean a delay in payment, as the documents may be returned for amendment.
3. Only out of pocket expenses wholly, exclusively and necessarily incurred for college business may be claimed.

PAYEE

TITLE | INITIALS | SURNAME (as appears on bank account)

CONFIRMATION OF STATUS

STAFF ONLY	STUDENT ONLY	NEITHER
Payroll no	Student no	Address
Department	Department	Post Code
Building	Building	BANK DETAILS FOR FASTER PAYMENT
Campus	Campus	SORT CODE - -
E-Mail	E-Mail	ACCOUNT NUMBER

PURPOSE OF EXPENSE (ie TRIP, CONFERENCE etc)

VIRTUAL REALITY STUDY PARTICIPATION

Details of Expenses - Please attach ALL receipts. Please note that a credit card slip is NOT a valid receipt.

For foreign currency items, convert and show exchange rate used, or claim sterling charged to credit card

Mileage Claim (show details on attachment if insufficient space)

for current College mileage rates see http://www.kcl.ac.uk/about/structure/admin/finance/staff/mileagerates.html

Date	From	To	Mileage	Pence/m	Amount £	P

Other Expense Claims (show details on attachment if insufficient space)

Date	Details	£	P
	VIRTUAL REALITY STUDY PARTICIPATION	10	00
	TOTAL CLAIMED (INCLUDING MILEAGE) £	10	00

ACCOUNT CODES

(Nominal code and subjectives **MUST** be completed)

Total MUST equal total of expenses above.

Claimants Signature _____

Date D D M M Y Y

Authorised Signatory _____

Print Name _____

Telephone No. _____

KING'S College LONDON

VIRTUAL REALITY AND SOCIAL SITUATIONS STUDY
Confirmation of Participation

PARTICIPANT NUMBER: ☐

I confirm that I have participated in the Virtual Reality & Social Situations study (Stage 2: Virtual Reality) at the Institute of Psychiatry, Psychology & Neuroscience, King's College London.

NAME of participant: .....

SIGNATURE of participant: .....

DATE: .....

I confirm that the person named above has participated in the Virtual Reality & Social Situations study (Stage 2: Virtual Reality) at the Institute of Psychiatry, Psychology & Neuroscience, King's College London.

NAME of researcher: .....

SIGNATURE of researcher: .....

DATE: .....

3. Evaluating pre-therapy rates of prescribed psychotropic medication and post-therapy outcomes in a South London IAPT service over a 7 year duration

Simon Riches

King's College London, Institute of Psychiatry, Psychology & Neuroscience
Department of Psychology

ABSTRACT

***Background*:** Psychological therapies are the NICE-recommended first line treatment for common mental health problems. However, psychotropic medication is frequently prescribed before psychological therapy. In order to inform decisions about the mental health care provisions in the London borough of Southwark, an analysis of pre-therapy rates of prescribed psychotropic medication and post-therapy outcomes in the Southwark Improving Access to Psychological Therapies (IAPT) service was undertaken. This provides initial research required in order to develop a protocol for a medication support intervention for Southwark IAPT clinicians. ***Method*:** Routine service data was accessed and analysed using IAPTus Hypercube. Data accessed was medication prescription and adherence rate on entry to the service, overall and by year; demographics of prescribed patients, and pre-/post-therapy change for prescription rate, depression, anxiety, and general functioning. ***Results*:** 44% of patients entering Southwark IAPT between 2008 and 2014 (N=21,254) were prescribed medication at assessment. There was a significant yearly upward trend from 39% in 2008 to 46% in 2014. Overall, 11% of patients were medication non-adherent. Patients who are white, middle-aged, and unemployed or long-term sick or disabled were most likely to be prescribed on entry. The vast majority of patients retained their prescription status post-therapy, although the shift from prescribed to non-prescribed was slightly greater than from non-prescribed to prescribed. Symptoms for depression, anxiety and deficits in general functioning were all greater in prescribed patients on entry. The depression and general functioning change was higher in patients who were prescribed on entry, whereas the anxiety change was higher in patients who were non-prescribed on entry. ***Discussion*:** There are challenges implementing the NICE recommendation in Southwark. Opportunities for Southwark IAPT to offer greater support for people likely to be prescribed psychotropic medication are discussed.

KEY WORDS · IAPT · psychotropic medication · antidepressants · depression · anxiety

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Acknowledgements

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1. INTRODUCTION

1.1 Background

A quarter of adults experience a common mental health problem each year in the UK. Treatment provision for this issue faces considerable psychological, social and economic challenges. Mental health problems cost the UK economy £70bn in treatment provision, which amounts to 4.5% of gross domestic product (OECD, 2014). In terms of treatment provision, psychological therapies have been recommended by the National Institute for Health and Care Excellence (NICE) as the first line of treatment for common mental health disorders, not only for their efficacy in treating common mental health problems but also for their cost efficiency (NICE, 2011). In particular, cognitive behaviour therapy (CBT) has been shown to be an effective psychological treatment for common mental health problems (Butler et al., 2006; Hofmann et al., 2012; Linden et al., 2004). In the mid-2000s, an economic case argued for the wider availability of CBT treatment (Layard et al., 2007). Since its introduction in 2008, the Improving Access to Psychological Therapies (IAPT) programme has aimed to implement the NICE guidelines in England by providing cost-effective first-line evidence-based psychological treatment for common mental health problems (Clark et al., 2009; Gyani et al., 2013). According to IAPT, the programme is estimated to save the NHS up to £272 million and the wider public sector more than £700 million.

Limited funding for mental health provisions in the UK (highlighted in a co-authored letter to NHS England by such organizations as Mind and Rethink Mental Illness, the Royal College of Psychiatrists and the Mental Health Network in March 2014) has meant that patients referred to IAPT services have encountered long waiting times between their initial referral to IAPT and commencing psychological treatment (HSCIC, 2015). This outcome has important consequences for the care pathway. Although many IAPT services offer self-referral as an alternative route of entry, GPs remain the main gateway for patients to enter mental health treatment. GPs can offer patients psychotropic medication and/or referral to psychological services to receive psychological therapy. NICE observe that limited provision of psychological interventions has meant that psychotropic medication is generally employed as the most common method of treatment for common mental health disorders in primary care, rather than psychological treatment (NICE, 2011).

UK psychotropic medication prescription rates have increased in recent decades. A study of the general practice research database revealed that antidepressant prescribing nearly doubled between 1995 and 2004 (Moore et al., 2009). More recently, the Nuffield Trust and Health Foundation's Quality Watch report found a 165% increase in antidepressants prescribing in England between 1998 and 2012, an average of 7.2 per cent a year, which escalated in particular after the 2008 financial crisis (Spence et al., 2014).

Failure to meet the NICE guidelines on implementing psychological therapies for common mental health problems is not the only challenge faced by health services and policymakers. Medication 'non-compliance' or 'non-adherence', i.e. patients not taking the medication that they have been prescribed, is a longstanding problem with antidepressants (Cramer et al., 2008), which has important psychological and social consequences for patients, in terms of providing appropriate treatment provision, as well as economic consequences for the cost efficiency of NHS spending.

The challenge of implementing the NICE guidelines for psychological therapies with limited funding is an issue for NHS services throughout the UK. These challenges raise important questions about the number of patients receiving medication rather than psychological therapy, and the extent of medication non-adherence. The present study evaluates the extent to which the NICE guidance of recommending psychological therapies as the first line of treatment for common mental health problems is implemented in a South London IAPT service. Southwark IAPT is a service that has been offering psychological support and therapy for adults with common mental health problems such as depression and anxiety since its inception in 2008. It offers individual and group psychological therapy, primarily CBT, although other approaches are provided; and is situated in the London borough of Southwark, which is a multicultural area of high population density. Southwark has a population estimate of 288,300 people, of which 49% are male and 51% are female, with a particularly large proportion of the population of Southwark aged between 25 and 34 (ONS, 2011). According to the Nuffield Trust and Health Foundation report, antidepressant prescription rates are generally lower in London when compared with the rest of the UK. Their analysis shows that Southwark Primary Care Trust prescribed 94.3 items per 1,000 people in quarter 3 of 2012/13. This contrasts with 71 items per 1,000 people in NHS Brent, which was lowest, and 331 items per 1,000 people in NHS Blackpool, which was highest (Spence et al., 2014).

1.2 Stakeholder Involvement

This study incorporated significant stakeholder involvement. Southwark IAPT has a Service User Feedback Forum at which staff members regularly consult service users to gain feedback on the service. The protocol for this study was presented by SR at the Service User Feedback Forum in March 2014. At this meeting, service user participants stated that they would like the service to provide greater support with medication cessation, side effects, withdrawal, and understanding how prescribed medication interacts with their psychological therapy. Participants highlighted that although psychotropic and therapeutic interventions are often presented collectively as 'treatments', there is often a disconnection between them, insofar as patients can end therapy but remain on antidepressants, which leaves patients without psychological support if they then discontinue medication. At this meeting it was agreed that the present study should identify the percentage of people who are prescribed

medication when they enter therapy at Southwark IAPT, in order to evaluate whether this is consistent with NICE guidance. In addition, it was agreed that a better understanding of medication adherence, the interaction of prescription rates with therapeutic outcomes, and demographic information of those prescribed medication on entry and discharge would enable Southwark IAPT to identify particular areas of concern and potential improvements within the service. It was agreed that if the present study could identify particular patient groups who may require greater support, then Southwark IAPT could use this data to carry out focus groups with specific patient groups in order to develop a protocol for a medication support intervention that could be delivered by Psychological Wellbeing Practitioners (PWPs). Such an intervention is not currently offered by Southwark IAPT.

The study protocol and the guidance from the Service User Feedback Forum were subsequently presented by SR to Southwark IAPT clinicians at a staff meeting in March 2014 in order to gain further feedback. The clinical staff agreed that the demographic information of those prescribed medication on entry would be important information for their clinical practice and that the development of a protocol for a medication support intervention would be an important addition to the service.

1.3 Study aims

The aims of the present study are to evaluate the pre-therapy rate of prescribed psychotropic medication, the demographics of those patients prescribed, and the post-therapy outcomes in the Southwark IAPT service. This will inform decisions about the mental health care provisions in Southwark, identify the needs for better integration within the whole healthcare system, especially between Southwark IAPT and GPs, and provide the initial research required in order to develop a protocol for a medication support that can be used by Southwark IAPT clinicians.

2. METHOD

2.1 Participants

Patients are referred to Southwark IAPT with predominantly depression and anxiety spectrum problems, as well as sleep, anger management, and low self-esteem. Patients are referred to other services if they have a current diagnosis of psychosis, personality disorders, drug or alcohol dependency and high risk to self. Southwark IAPT offers a wide range of treatment options, with CBT most prominent. In this study, psychological or therapeutic treatment can refer to individual high intensity CBT, guided self-help, couples counselling, Dynamic Interpersonal Therapy, Eye Movement Desensitization and Reprocessing, Interpersonal therapy, and Cognitive Analytical Therapy; Sleep issues, Stress, Confidence and Anger workshops; or psycho-educational groups for Panic, Anxiety and Depression, Depression, Mindfulness-based Cognitive Therapy, Mindfulness for long-

term health conditions, Compassion and relaxation training, post-natal depression, Changes for health; counselling, and behavioural couples therapy for depression.

2.2 Analysis

Data was accessed and analysed using the standard IAPT data analysis software programme IAPTus Hypercube, which is integrated with the IAPT electronic records system, IAPTus. The time period accessed was 2008 until 2014, using the date range of 1st January 2008 until 31st December 2014. This time period covers the commissioning of the Southwark IAPT service in 2008 and includes all data available on the Southwark IAPT minimum data set until the most recent full calendar year. All data was accessed and analysed in an anonymized form between 18th and 20th January 2015. Researchers manually calculated means and collapsed data categories using Microsoft Excel in order to produce data tables. IAPTus Hypercube Active Filters for all analyses are provided in the Appendix. Southwark IAPT collects data on prescribed medication at Session 1 rather than initial referral. Therefore, attendance at Session 1 of psychological therapy has been used as the time point at which patients are said to 'enter' the service. The present sample therefore includes the subset of referrals that engaged with the service and attended Session 1, not the total number of referrals.

Inferential statistics have been used to investigate significant differences. Due to the large sample size and the large number of tests, a significance level of $p<0.01$ is employed, in order to evaluate clinical importance. An online application (www.quantpsy.org) was used to calculate all Chi^2 analyses.

The analysis was conducted in four stages:

2.3 Stage 1 (Prescription rate on entry)

The number of patients prescribed and not prescribed medication on entry was identified, overall and by year. Southwark IAPT collects medication data in the categories of Prescribed and taking, Prescribed but not taking, Not Prescribed, Not stated (Person asked but declined to provide a response), and Unknown (Person asked and does not know or is not sure). In order to calculate the number of prescribed patients, the categories of 'Prescribed and taking' and 'Prescribed but not taking' were manually collated.

2.4 Stage 2 (Adherence)

Adherence and non-adherence rates were identified, overall and by year, within the category of those prescribed medication on entry. Southwark IAPT began recording medication adherence in 2011, so data is presented from this year forward.

2.5 Stage 3 (Demographics)

Demographics (gender, age, ethnicity, employment status) of those prescribed and non-prescribed on entry were identified. Southwark IAPT collects gender data in the binary categories of male and female, as well as recording if gender is unknown. Age data is collected by recording date of birth and IAPTus then calculates a patient's age. In preparing the data, two manual collations of data were produced. The first divided patients into young (aged ≤34 years), middle-aged (35-64 years) and older adults (≥65 years). The second divided patients by ten year ages ranges (≤19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79 and ≥80 years). Southwark IAPT collects ethnicity data in the categories of white, black or black British, Asian or Asian British, mixed, and other ethnic groups, as well as if ethnicity data is unknown by the patient, missing, or if the question is declined. Southwark IAPT collects employment data in the categories of employed full-time (FT), employed part-time (PT), student, retired, full-time homemaker or carer not seeking work, unpaid voluntary work and not seeking work, unpaid voluntary work and seeking work, unemployed and seeking work, unemployed and not seeking work and not receiving benefits, long-term (LT) sick or disabled receiving incapacity benefit/income support or both or employment and support allowance, and not stated (person was asked but declined to provide a response). In preparing the data, the categories of Unpaid voluntary work, not seeking work and Unpaid voluntary work, seeking work, and of Unemployed and seeking work and Unemployed, not seeking work, not receiving benefits have been manually collated and labeled as 'Unpaid volunteer' and 'Unemployed' respectively. Lack of knowledge of a psychotropic medication prescription or lack of willingness to disclose prescription is collected in the minimum data set. This was identified for each demographic in the analysis.

2.6 Stage 4 (Pre-/post-treatment changes)

Pre- and post-treatment changes in outcomes measures and prescription rate were analysed. Changes in prescription status were identified across four possible categories (i.e. from prescribed to prescribed, prescribed to non-prescribed, non-prescribed to prescribed, and non-prescribed to non-prescribed) for the total number of people who completed treatment (i.e. if they attended 2 or more treatment sessions).

Measures of depression, anxiety and social functioning were analysed pre- and post-therapy for those who were prescribed and non-prescribed. Southwark IAPT routinely uses the standard IAPT screening measures for initial screening and assessment and for ongoing assessment of patient outcomes. Pre- and post- matrices for the Patient Health Questionnaire (PHQ9), the Generalised Anxiety Disorder Assessment (GAD7), and the Work and Social Adjustment Scale (WSAS) were analysed to determine the effect of therapy on those prescribed and non-prescribed. Mean scores for first and last sessions were then manually calculated from the data in the pre- and post- matrices. The PHQ9 is a self-administered measure, which scores each of the 9 DSM-IV criteria on a 4-point scale, from

“0” (not at all) to "3" (nearly every day), for the most recent two weeks. An example item is ‘Little interest or pleasure in doing things’. The PHQ9 has been validated for use in primary care (Cameron et al., 2008). The GAD7 is a 7-item anxiety scale with good reliability, as well as criterion, construct, factorial, and procedural validity, which rates 7 items on a 4 point scale, from “0” (not at all) to "3" (nearly every day), for the most recent two weeks. An example item is ‘How often have you been bothered by feeling nervous, anxious or on edge?’ (Spitzer et al., 2006). The WSAS is a reliable and valid measure of general functioning, which scores on 5 items on a 9-point scale, from “0” (not at all) to "8" (very severely), for the most recent two weeks. An example item is ‘How much does your problem impair your ability to carry out home management (cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc)?’ (Mundt et al., 2002).

3. RESULTS

3.1 Sample

In total, 21,254 patients were included in the study. This was the total number of patients who entered therapy at Southwark IAPT between 2008 and 2014. 7,210 (34%) of these patients were male and 14,038 (66%) were female. The mean age was 38.62. In terms of ethnicity, 12,948 (61%) patients were white, 3,039 (14%) were black/black British, 676 (3%) were Asian/Asian British, 885 (4%) were mixed, 854 (4%) were from other ethnic groups, 208 (1%) declined to respond to a question about ethnicity, 28 (1%) did not know their ethnicity, and ethnicity data was missing in 2,616 (12%) cases. Diagnosis data was missing for 12,471 (58%) of all patients. See Table 1a (Appendix). When missing data is excluded, the data shows that 18% of patients had a depressive episode, 18% of patients had recurrent depressive disorder, 16% had mixed anxiety and depressive disorder, 11% had generalized anxiety disorder, 6% had post-traumatic stress disorder, 4% had social phobias, 4% had obsessive-compulsive disorder, 4% had adjustment disorders, 3% had panic disorder, and 16% had another diagnoses. See Table 1b (Appendix) and Figure 1.

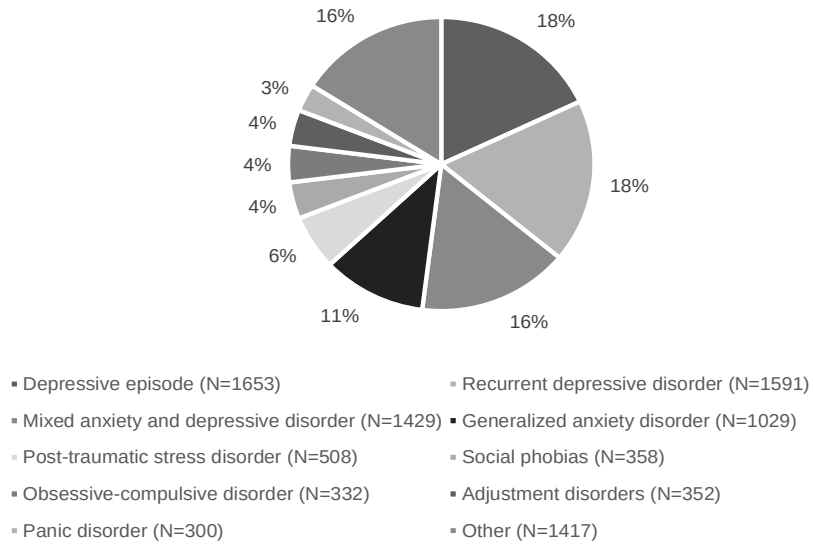

Figure 1. Patient diagnoses at entry, with missing data excluded

For the purpose of the Stage 4 analysis, the total number of people who completed therapy was 14,194.

Clinician data entry errors were discovered in less than 1% of cases. A manual scan of all 2008 data by researchers revealed that clinicians had recorded duplicate entries for first sessions in 2 cases out of the 242 total cases. Researchers inferred that a similar pattern of duplicate entries could explain data error in subsequent years. Missing data was recorded in all analyses.

3.2 Stage 1 (Prescription rate on entry)

In total, 9,352 (44%) patients had been prescribed medication on entry to Southwark IAPT. The prescription rate was 39% in 2008, 40% in 2009, 40% in 2010, 43% in 2011, 44% in 2012, 45% in 2013, and 46% in 2014. In total, 11,158 (52%) patients were non-prescribed on entry. The remaining patients either declined to state if they were prescribed medication (3%) or did not know (1%). See Table 2 (Appendix) and Figure 2.

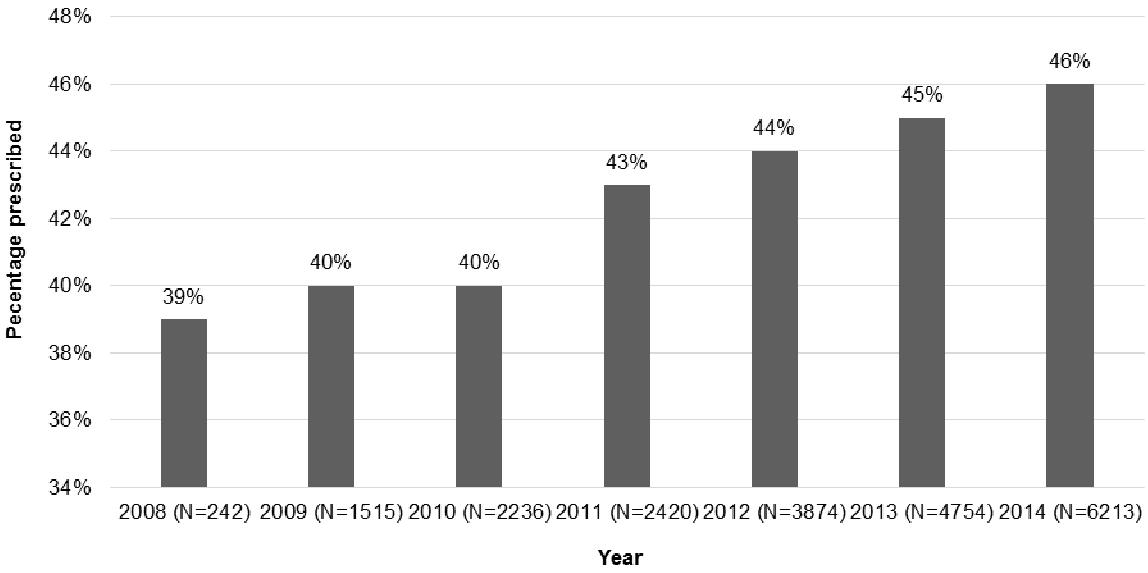

Figure 2. Percentage of prescribed patients, by year 2008-2014

Chi^2 analysis shows that the prescription rate differences between the years 2010-2013 and 2010-2014 were statistically significant, at $p<0.01$ and $p<0.001$ respectively.

3.3 Stage 2 (Adherence)

In total, 6,910 (89%) prescribed patients were medication adherent and 847 (11%) were medication non-adherent. Divided by year, non-adherent patients totaled 33 (3%) in 2011, 195 (11%) in 2012, 263 (12%) in 2013, and 356 (12%) in 2014. See Table 3 (Appendix) and Figure 3.

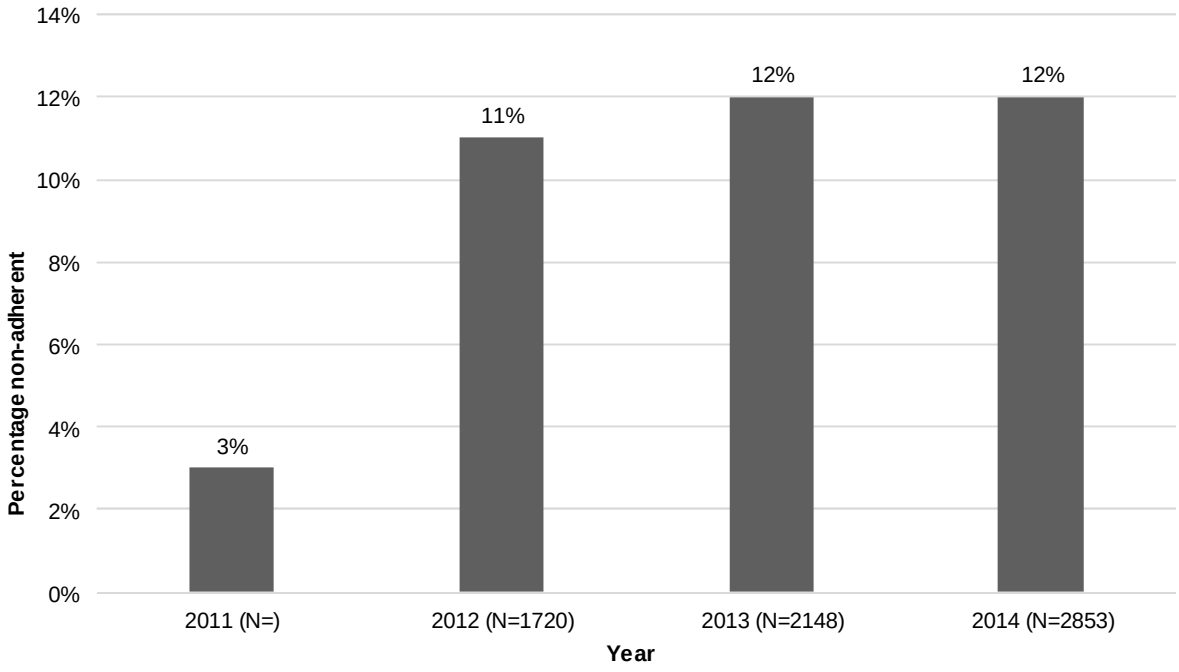

Figure 3. Non-adherence on entry in prescribed patients, by year 2011-2014

Chi^2 analysis shows that the prescription rate differences between the years 2011-2012, 2011-2013 and 2011-2014 were statistically significant, all at $p<0.001$. Note that Southwark IAPT began recording medication adherence during 2011 so some people may not have been asked this question during this year.

3.4 Stage 3 (Demographics)

Gender

3,232 (45%) male patients and 6, 119 (44%) female patients were prescribed on entry. See Table 4 (Appendix) and Figure 4.

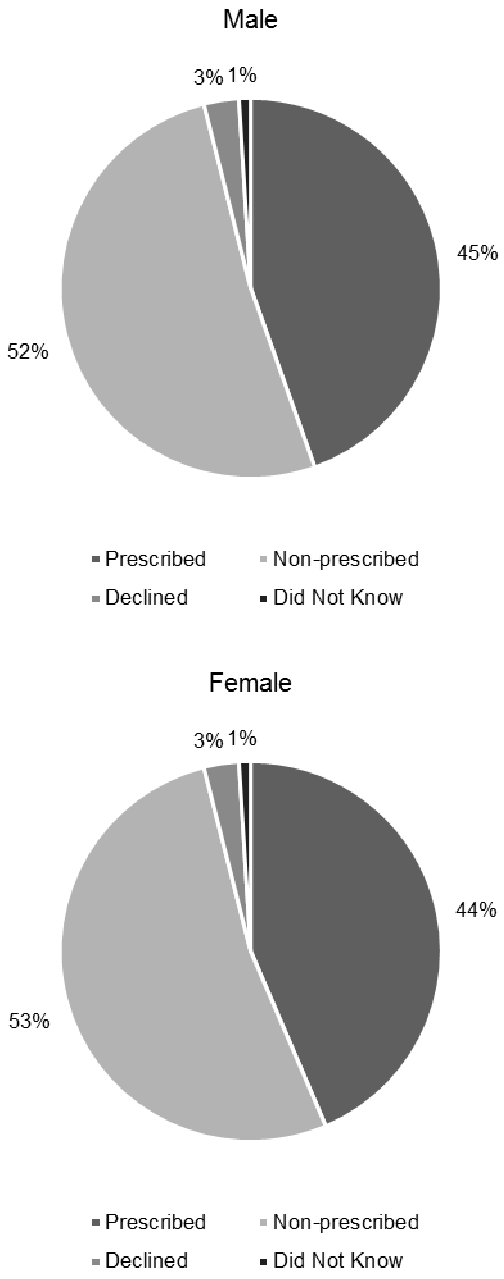

Figure 4. Prescribed and non-prescribed patients by gender

Chi^2 analysis showed that the prescription rate difference between males and females was not significant.

Age

3,634 (38%) young people, 5,414 (50%) middle-aged people, and 303 (37%) older people were prescribed medication on entry. See Table 5a (Appendix) and Figure 5a.

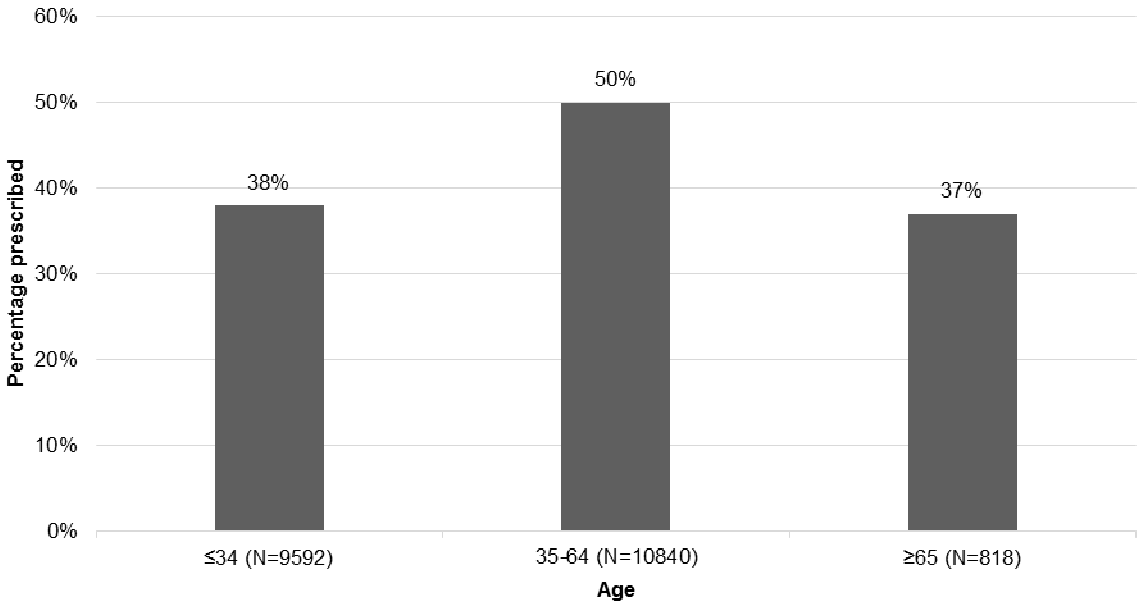

Figure 5a. Age of prescribed patients on entry, by younger, middle-aged and older adults

Chi^2 analysis showed a statistically significant difference between younger people and middle-aged people, and between middle-aged people and older people, both at $p<0.0001$.

When the data was divided into by ten year age ranges, 134 (27%) ≤19 year olds, 2,203 (38%) 20-29 year olds, 2,443 (41%) 30-39 year olds, 2,345 (50%) 40-49 year olds, 1,614 (56%) 50-59 year olds, 445 (48%) 60-69 year olds, 128 (36%) 70-79 year olds, and 39 (29%) ≥80year olds were prescribed on entry. See Table 5b (Appendix) and Figure 5b.

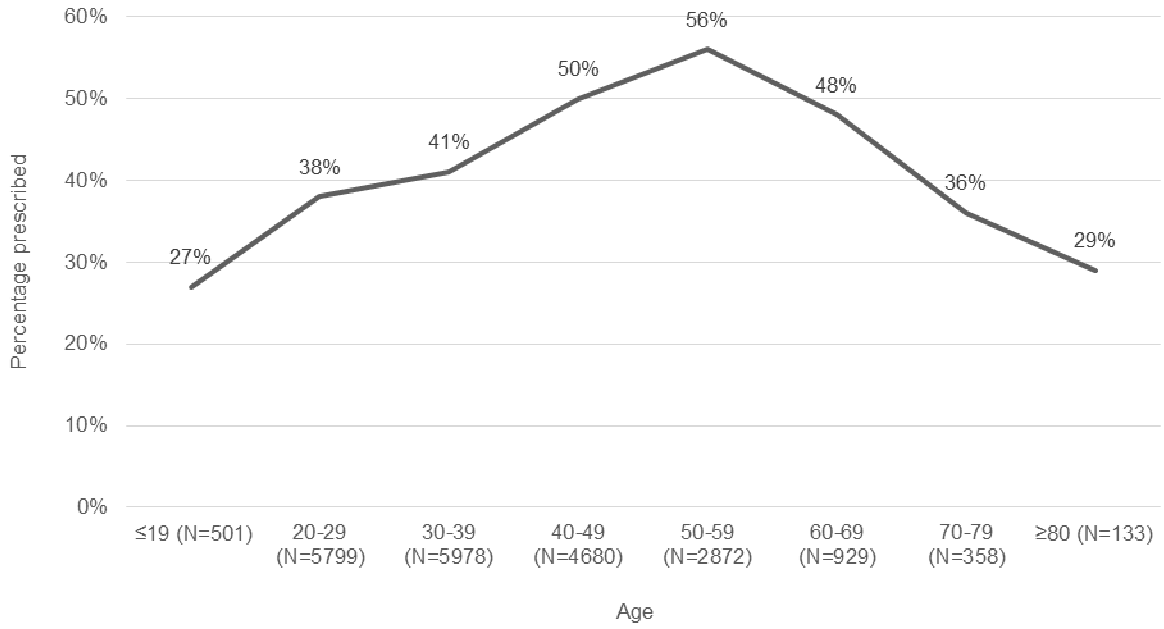

Figure 5b. Age of prescribed patients on entry, by ten-year age ranges

Chi^2 analysis showed that the differences are statistically significant at $p<0.001$. The trend line goes up and then down again.

Ethnicity

6,009 (46%) White patients, 1,225 (40%) Black/Black British patients, 352 (40%) Mixed patients, 344 (40%) Other patients, and 260 (36%) Asian patients were prescribed on entry. Ethnicity data was missing for 2,616 (12%) patients. See Table 6 (Appendix) and Figure 6.

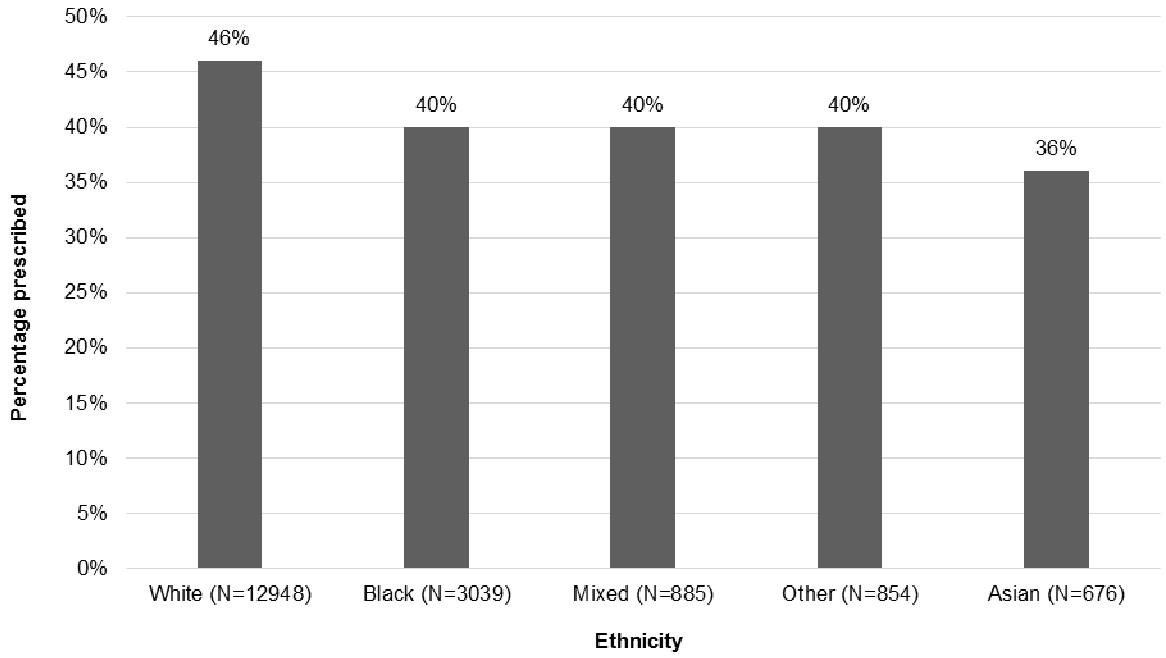

Figure 6. Ethnicity of patients prescribed on entry

Chi^2 analysis showed that there is a statistically significant difference in prescription rates on entry between the White and the Black/Black British, Asian, Mixed, and Other groups, all at $p<0.01$.

Employment

1,714 (71%) long term sick patients or disabled patients, 2,046 (51%) unemployed patients, 75 (44%) unpaid volunteer patients, 508 (43%) fulltime homemakers or carer patients, 408 (42%) retired patients, 3,032 (37%) fulltime employed patients, 957 (37%) part-time employed patients, and 556 (37%) student patients were prescribed on entry. See Table 7 (Appendix) and Figure 7.

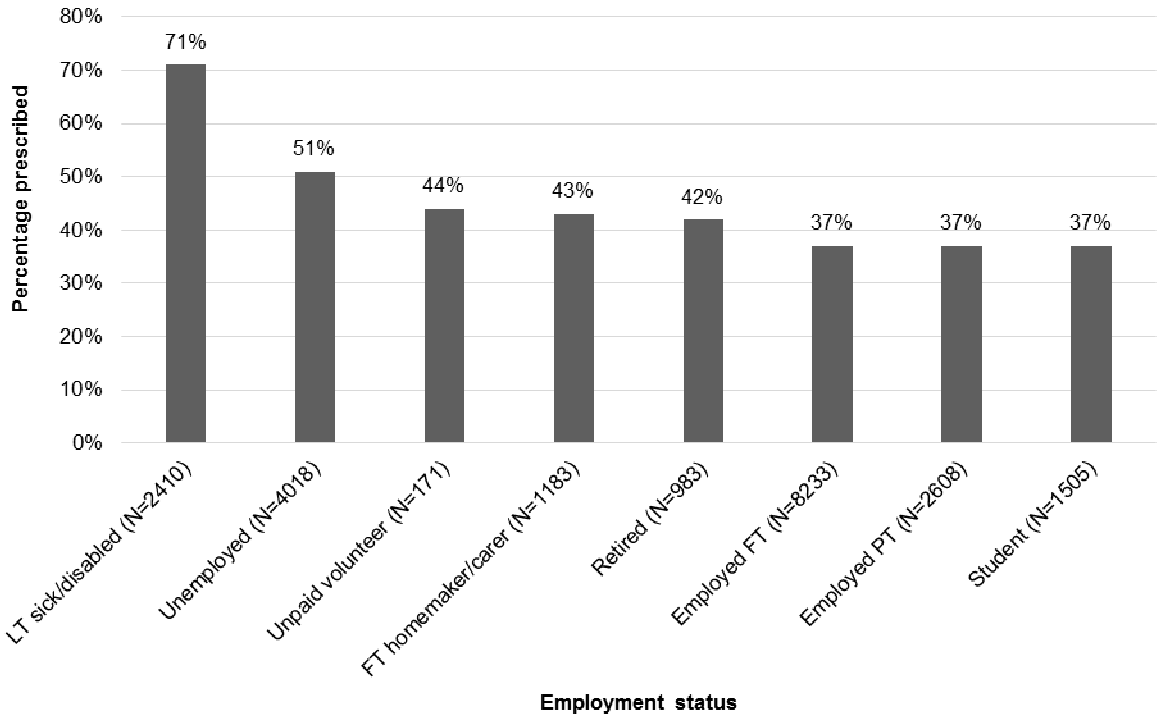

Figure 7. Employment status of prescribed patients on entry

Chi^2 analysis showed that there is a statistically significant difference in prescription rates between people who are long term sick or disabled and all other employment statuses, at $p<0.005$.

Knowledge of prescription and willingness to disclose

Overall, 550 (3%) people declined to state if they were prescribed psychotropic medication and 194 (1%) did not know. By year, 17 (7%) people in 2008, 111 (7%) people in 2009, and 133 (6%) people in 2010 declined to state if they were prescribed medication. This figure remained at 3% or lower from 2011 onwards. 142 (4%) unemployed people, 45 (5%) retired people, 41 (5%) older adults, 36 (4%) 60-69 year olds, 20 (6%) 70-79 year olds, and 7 (5%) ≥80 year olds declined to state if they were prescribed medication. 30 (6%) people of Other ethnicity and 12 (6%) people who declined to give their ethnicity declined to state if they were prescribed medication. 11 (2%) Asian people did not know if they were prescribed medication. In all other categories, figures for declining to state if they were prescribed medication or for not knowing about being prescribed medication remained at or below the total sample figures of 3% and 1% respectively.

3.5 Stage 4 (Pre-/post-treatment change)

Prescription rate

Overall, 6,354 (45%) patients were non-prescribed on entry and remained non-prescribed on discharge; 4,701 (33%) were prescribed on entry and remained prescribed on discharge;

1,293 (9%) were prescribed on entry and non-prescribed on discharge; and 906 (6%) were non-prescribed on entry and prescribed on discharge. See Table 8 (Appendix) and Figure 8.

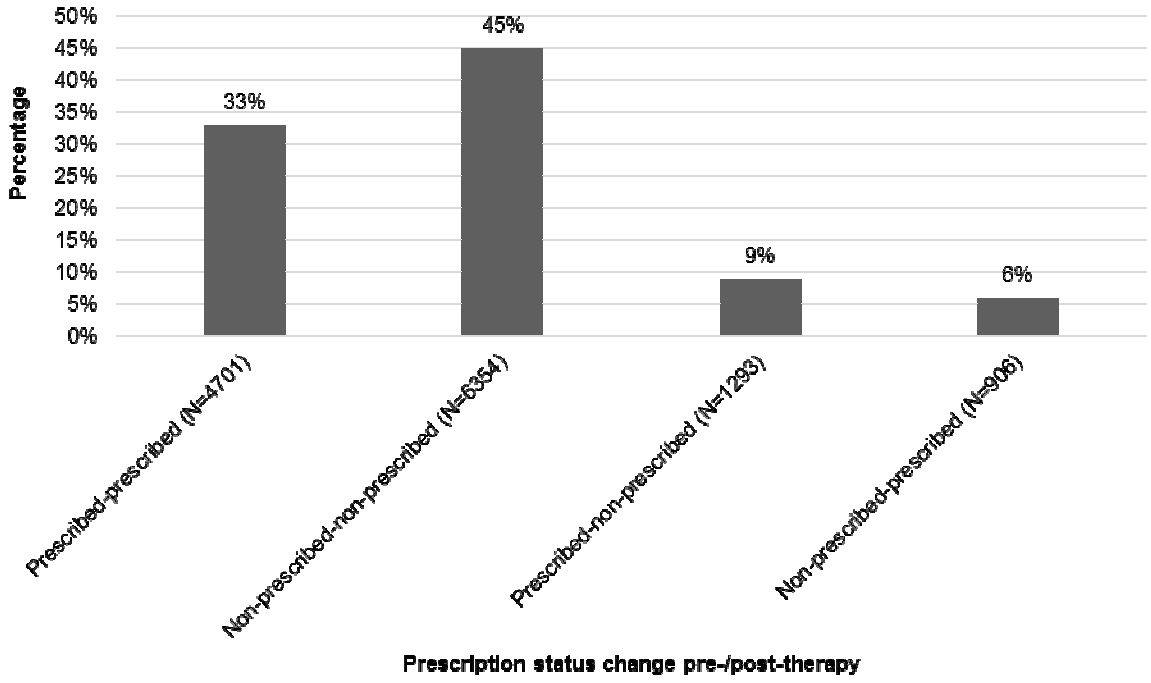

Figure 8. Prescription status change pre-/post-therapy

Outcome Measures

The mean score for depression (PHQ9) was higher in prescribed patients (16.08) on entry than it was for non-prescribed patients (12.26). The mean score for anxiety (GAD7) was higher in prescribed patients (13.36) on entry than it was for non-prescribed patients (11.16). The mean score for general functioning (WSAS) was higher in prescribed patients (19.71) on entry than it was for non-prescribed patients (15.42). See Table 9 (Appendix) and Figure 9a.

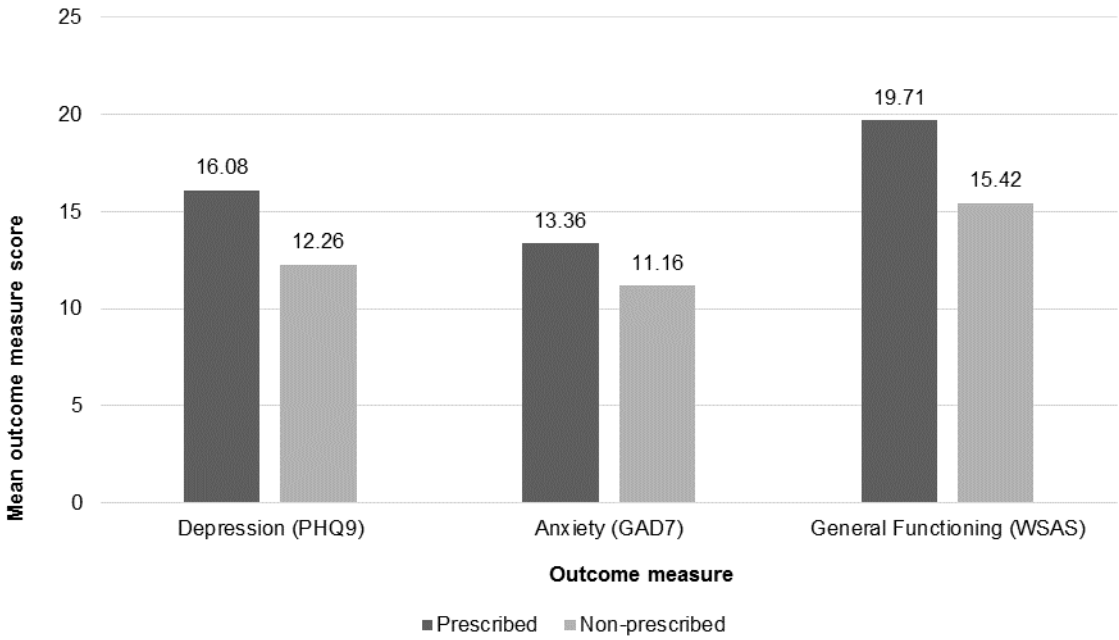

Figure 9a. Mean outcome measure scores on entry for prescribed and non-prescribed patients

The post-treatment change in depression is greater in prescribed patients (-4.46) than it is in non-prescribed patients (-3.73); whereas, in anxiety, it is greater in non-prescribed patients (-3.39) than in prescribed patients (-3.29). The post-treatment change in social functioning is greater in prescribed patients (-3.75) than it is in non-prescribed patients (-3.57). See Table 9 (Appendix) and Figure 9b.

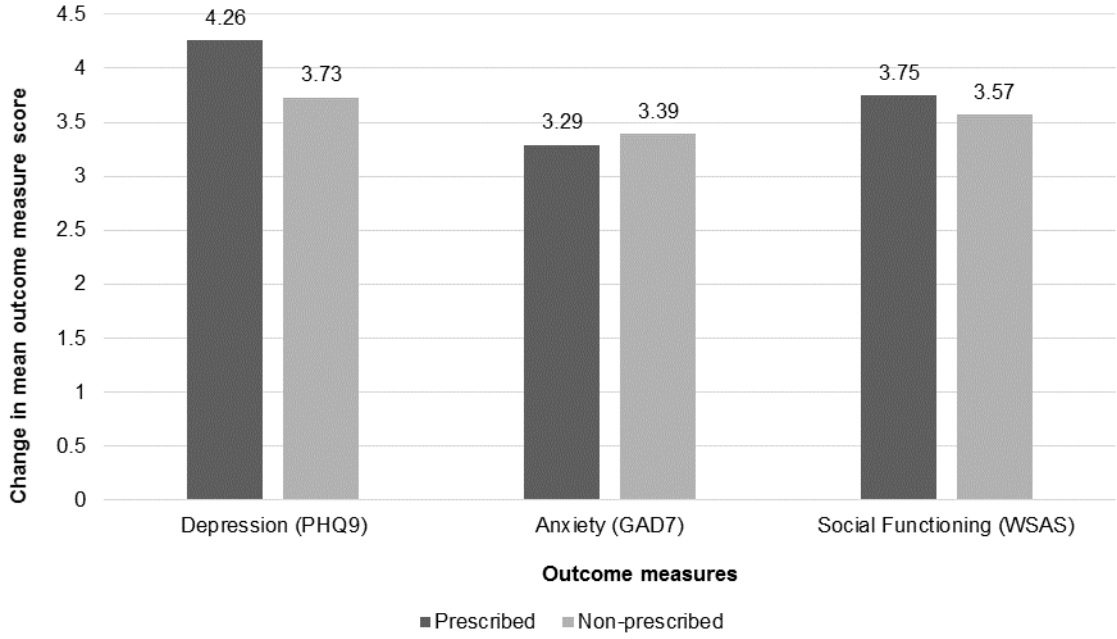

Figure 9b. Post-treatment improvement in mean outcome measure scores for prescribed and non-prescribed patients

4. DISCUSSION

4.1 Prescription rate

NICE recommendations for psychological therapy as the first line treatment for mild to moderate mental health problems are a challenge for Southwark. Nearly half of all patients entering therapy at Southwark IAPT between 2008 and 2014 were prescribed psychotropic medication when entering psychological treatment. Prescription rates of psychotropic medication of those entering therapy increased yearly in all but one year from 2008 to the most recent calendar year, with the highest proportion of patients in the history of the service prescribed medication when they entered therapy in 2014. Although the prescription rate increase plateaued from 2011 to 2014, there was a statistically significant increase after 2010.

Although Southwark is a borough of comparatively fewer psychotropic medications prescriptions, it still appears to be characteristic of recent national increases in psychotropic prescriptions rates, with GPs prescribing medication to combat long waiting lists for psychological therapy. Furthermore, as a deprived, inner city borough, there may be greater severity of mental health problems within the Southwark population, in which case the prescription rate for Southwark IAPT may reflect the NICE recommendation of dual treatments for severe depression (NICE, 2011). Future research may investigate the symptom severity at Southwark IAPT.

4.2 Adherence

Medication non-adherence was found to be a challenge for Southwark services. Non-adherence at entry to Southwark IAPT has been greater than 10% since 2012. Although medication non-adherence has plateaued since 2012, there was a statistically significant increase after 2011. So although the evidence suggests that this problem is not increasing, the non-adherence rate raises questions about the medication support that Southwark IAPT might offer to patients in future, as well as economic concerns for local NHS services about unused medical resources. For example, this study found that nearly a thousand people in Southwark were being prescribed psychotropic medication that they were not taking between 2011 and 2014, and this figure includes only that subset of the Southwark population who entered psychological treatment at Southwark IAPT during these years.

4.3 Demographics

Gender

The prescription status profiles for males and females profiles are very similar, which suggests that gender is not a notable factor in psychotropic medication prescription rates within Southwark.

Age

Middle-aged people were most likely to be prescribed psychotropic medication on entry to psychological therapy at Southwark IAPT, especially those in the 50-59 year old age range. When the data was divided into ten year age ranges, the youngest and oldest adults were least likely to be prescribed, with 27% of ≤19 year olds, and 29% of ≥80 year olds prescribed on entry. This suggests that middle-aged people are a group who might benefit from medication support in Southwark IAPT.

Ethnicity

NHS policy aims to improve mental health outcomes for BME communities. The Department of Health has highlighted ethnic inequalities in mental health service experience and outcome (NHS, 2003). More recently commissioner guidance included identifying and implementing specific measures to reduce ethnic inequalities in mental health (JCP-MH, 2014). The results of the present study raise further questions about whether inequalities are being addressed given that White patients were statistically more likely to be prescribed on entry, than Black/Black British, Mixed, Other, and Asian/Asian British patients. The discrepancy in ethnicity and prescription status is a notable finding. However, it is impossible to determine from these results whether GPs have been less likely to prescribe psychotropic medication to BME communities or whether BME communities are less likely to accept psychotropic prescriptions. Furthermore, the 12% missing ethnicity data represents a limitation of the findings. However, future research may seek to understand the experience

of different ethnic groups with regard to being offered and prescribed psychotropic medication.

Employment

There is strong evidence that employment is generally good for psychological wellbeing and recovery from mental health conditions (Slade, 2012; Waddell & Burton, 2006) and that unemployment can have a detrimental effect on mental health (Paul & Moser, 2009). The findings of this study are consistent with this research and noteworthy in the light of the original economic case for the IAPT programme. According to that case, increased access to psychological therapies would 'pay for itself' by reducing public costs (benefits, medical costs) and increasing revenues (taxes from return to work, increased productivity, etc.) (Clark, 2011). The study highlights that long term sick or disabled and unemployed patients are highly likely to be prescribed medication and therefore on dual treatments. This finding shows that they remain a key target group for IAPT to access, as well as highlighting the important role for vocational specialists working within IAPT.

4.4 Pre-/post-treatment change

Prescription rate

Overall, the vast majority of patients retained their pre-treatment prescription status at discharge (i.e. the 45% who were non-prescribed and the 33% who were prescribed pre- and post-treatment). Far fewer were no longer prescribed at discharge or had gained a medication prescription during therapy. A slightly greater proportion moved from prescription to non-prescription, rather than from non-prescription to prescription, although this difference was small (9% compared with 6%). Overall, this study suggests there is little relationship between psychological therapy and prescription status change. However, it is important to consider that IAPT clinicians are focused on improving clinical outcomes, as typically measured by the PHQ9 and GAD7. It is not among their aims to address prescription status and dual treatment is recommended in more severe cases (NICE, 2011).

Outcome Measures

The mean scores for depression, anxiety and general functioning are all higher in prescribed patients on entry, which is likely to reflect greater severity of symptoms on all three measures in those who are prescribed. This outcome is consistent with the assumption that those prescribed medication are likely to have more severe symptoms. Post-treatment, prescribed patients improve more on depression and social functioning, whereas non-prescribed patients improve more on anxiety. However, the differences on all measures are very small. This suggests that improvement rates in psychological therapy were not affected by prescription status.

Knowledge of prescription and willingness to disclose

Patients' willingness to disclose their prescription status is another important area. The study shows that patients have generally become more likely to disclose whether they are prescribed medication since 2008. Older adults and patients who are retired were marginally more likely to decline to state their prescription status. This may raise questions about whether stigma and sensitivity about psychotropic medication use is especially pronounced in older adults. This may be important for IAPT clinicians to consider, as well as an area for future research, especially as a recent meta-analysis found that late life depression is common (Luppa et al., 2012). However, older adults are also more likely to be taking medication for many conditions and, therefore, it may be more difficult for them to know whether a specific medication is for a mental or physical health condition.

4.5 Limitations

The study has several limitations given the homogeneity and heterogeneity of the sample. Firstly, Stage 4 of our analysis does not distinguish between the patient treatments. Although Southwark IAPT predominantly delivers CBT, there are a wide variety of psychological treatments, both in individual and group therapy, and for varying durations, undertaken by participants in the study. Some patients may have received more than one course of treatment. However, all patients received an evidence-based, IAPT-approved psychological treatment. Secondly, the study does not distinguish between different psychotropic medications or dosage. The Royal College of Psychiatrists cites almost thirty different kinds of antidepressants available in the UK today, although there are five main types: SSRIs (Selective Serotonin Reuptake Inhibitors), SNRIs (Serotonin and Noradrenaline Reuptake Inhibitors), NASSAs (Noradrenaline and Specific Serotoninergic Antidepressants), Tricyclics and MAOIs (Monoamine oxidase inhibitors). Participants are likely to be prescribed one of these medications. However, IAPTus Hypercube data analysis software does not provide direct comparisons of different medications with other factors. This is because recording the precise medication prescribed is not part of the IAPT minimum data set, even though clinicians may enter this data in their clinical notes. Thirdly, although most patients presented with depression or anxiety disorders, the fact that more than half of diagnosis data is missing means that we cannot draw diagnosis-specific conclusions. Fourthly, IAPT services modified their admission criteria during the time period under analysis so they were not always accessing on the same community groups.

Further limitations apply to the way that IAPT services record clinical data. Firstly, Southwark IAPT collects routine data on prescribed medication at Session 1 rather than initial referral. The present sample therefore includes the subset of referrals that engaged with the service and attended Session 1, not the total number of referrals. In certain cases Southwark IAPT collects demographic information at initial referral, so a slight time discrepancy may occur

between these two sets of data. In the case of age, it is important to take this into account when comparing age with prescription. Although waiting lists times may impact on prescription rates, Southwark IAPT does not record waiting list times in a way that they can be directly compared with prescription rates. Future studies could examine the relationship between waiting list duration and psychotropic medication prescription. However, that is beyond the remit of the present study.

4.6 Clinical applications and future research

The findings of this study offer guidance on how Southwark IAPT could offer greater support for people likely to be prescribed psychotropic medication. Given that nearly half of all patients are prescribed psychotropic medication on entry to the service, Southwark IAPT could link with medical practitioners to discuss psychotropic medication issues and provide specialist support for patients. The service currently offers pre-therapy orientation sessions for patients on the waiting list which could incorporate further education about psychotropic medication. It could also be important to provide training on psychotropic medication for existing Southwark IAPT staff.

As the most likely to be prescribed medication when entering psychological treatment in Southwark IAPT, people who are unemployed or long-term sick, middle-aged, and white would make an appropriate target for participants to take part in focus groups to explore their views on medication, their experience with GPs' prescribing medication and making referrals for psychological therapy, and to develop protocols for medication support. Focus groups with BME communities and with service users on medication at the beginning and end of treatment could also provide further important data. Further statistical analysis could investigate the age effect and the long-term sick group.

PWPs could take on further responsibilities to support medication adherence. Such protocols may aim to take into account any stigma or sensitivity in discussing medication, especially with older adults as they are less likely to disclose medication prescription. In relation to adherence, future research might further investigate non-adherence by surveying a sample of non-adherent patients to ascertain reasons for non-adherence. This research may consider whether patients do not find their medication effective, have worries about side effects, or other fears about psychotropic medication. This study shows that it is vital that GPs and IAPT are closely connected. A focus group of local GPs exploring prescribing habits for common mental health problems would be of interest in investigating the provision of treatment for patients.

4.7 Dissemination

This service evaluation project will be fed back to the clinical team, to local GPs, and to senior boards within the SLaM Trust.

4.8 Leadership

This service evaluation provided an excellent opportunity to develop leadership skills. It was important to engage the clinical team in the project, and to deliver presentations to both the clinical team and to service users. It also provided an excellent opportunity to liaise with and work directly with members of the team at all levels, as well as with the developers of IAPTus Hypercube, in order to arrive at a thorough understanding of the data. This role enabled me to learn about how this data can differ in relevance to staff who work, for example, at high intensity therapy, low intensity therapy, or employment support. The findings will influence change within the team by providing materials for a medication support protocol that can be implemented by PWPs, and by providing data that can inform discussions at board level so that Southwark IAPT and local GPs can work together to address the issues that have been identified.

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Appendix I IAPTus Hypercube active filters, data tables, and inferential statistics

The use of IAPTus filters simplifies the selection of relevant participants for the study. Each filter is selected to ensure that only relevant clients are included in the dataset. To ensure accuracy, there is often overlay of certain filters to ensure the appropriate information is collected. Each filter was clarified with an administrator from Mayden House, the company that designed and offers support for the IAPTus system. The following is an explanation of the Active Filters that were used:

Treatment Type: IAPT

This filter ensures that only including patients from IAPT treatment rather than non-IAPT treatment, i.e. vocational support, are included in the study.

MDS/Non-MDS clinical contacts

Each clinical session can be stored as a minimum data set (MDS) session or a non-MDS. The latter tends to be used by clinicians when there has not been a therapeutic contact but information which would be important to share is collected and recorded.

MDS Clinical Sessions

This filter ensures the selection of only MDS clinical contacts.

IAPT Psychotropic Medication Usage:

This filter provides a breakdown of the use of prescribed medication for the clinical contact In this case, the options are 'Prescribed and taking'; 'Prescribed but not taking'; 'Not Prescribed'; 'Not stated (Person asked but declined to provide a response)'; 'Unknown (Person asked and does not know or is not sure)'.

Employment Psychotropic Medication Usage

This filter is automatically displayed by IAPTus Hypercube when using the IAPT Psychotropic Medication Usage filter.

Complete vs Incomplete sessions: Show Complete Sessions only

This filter ensures that the data only includes clinical contacts which have collected the MDS criteria and, therefore, excludes incomplete clinical contacts.

IAPT Attendance

This filter ensures that only sessions when the client attended (even if late) are included. In this case the options included are: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen; Employment Attendance.

Table 1a. Diagnosis of patients 2008-2014

Diagnosis	N (%)
F10 - Mental and behavioural disorders due to use of alcohol	49 (0%)
F31 - Bipolar affective disorder	39 (0%)
F32 - Depressive episode	1653 (8%)
F33 - Recurrent depressive disorder	1591 (7%)
F40.0 - Agoraphobia (with or without history of panic disorder)	260 (1%)
F40.1 - Social phobias	358 (2%)
F40.2 - Specific (isolated) phobias	122 (1%)
F41.1 - Generalized anxiety disorder	1029 (5%)
F41.2 - Mixed anxiety and depressive disorder	1429 (7%)
F42 - Obsessive-compulsive disorder	332 (2%)
F43.1 - Post-traumatic stress disorder	508 (2%)
F45 - Somatoform disorders	83 (0%)
F50 - Eating disorders	56 (0%)
F99 - Mental disorder, not otherwise specified	194 (1%)
Z63.4 - Disappearance and death of family member	115 (1%)
F41.0 - Panic disorder (episodic paroxysmal anxiety)	300 (1%)
F34.1 - Dysthymia	26 (0%)
F43.2 - Adjustment disorders	352 (2%)
F45.2 - Hypochondriacal disorder	85 (0%)
F12 - Mental and behavioural disorders due to use of cannabinoids	10 (0%)
F19 - Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances	16 (0%)
F20 - Schizophrenia	4 (0%)
F21 - Schizotypal disorder	1 (0%)
F22 - Persistent delusional disorders	4 (0%)
F23 - Acute and transient psychotic disorders	7 (0%)
F34 - Persistent mood (affective) disorders	100 (0%)
F43 - Reaction to severe stress and adjustment disorders	175 (1%)
F48 - Other neurotic disorders	24 (0%)
F52 - Sexual dysfunction not due to a substance or known physiological condition	8 (0%)
F60 - Specific personality disorder	17 (0%)
F63 - Habit and impulsive disorders	15 (0%)
F64 - Gender identity disorders	3 (0%)
F90 - Hyperkinetic disorder	4 (0%)
Missing	12471 (58%)
Total	21440

Table 1b. Diagnosis of patients 2008-2014 with missing data excluded

Diagnosis	N (%)
F32 - Depressive episode	1653 (18%)
F33 - Recurrent depressive disorder	1591 (18%)
F41.2 - Mixed anxiety and depressive disorder	1429 (16%)
F41.1 - Generalized anxiety disorder	1029 (11%)
F43.1 - Post-traumatic stress disorder	508 (6%)
F40.1 - Social phobias	358 (4%)
F42 - Obsessive-compulsive disorder	332 (4%)
F43.2 - Adjustment disorders	352 (4%)
F41.0 - Panic disorder (episodic paroxysmal anxiety)	300 (3%)
Other	1417 (16%)
Total	8969

Table 2. Prescription status for patients on entry, in total and by year

Year	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
008	242	94 (39%)	131 (54%)	17 (7%)	0 (0%)
2009	1515	604 (40%)	799 (53%)	111 (7%)	1 (0%)
2010	2236	897 (40%)	1206 (54%)	133 (6%)	0 (0%)
2011	2420	1036 (43%)	1306 (54%)	74 (3%)	4 (0%)
2012	3874	1720 (44%)	2032 (52%)	75 (2%)	47 (1%)
2013	4754	2148 (45%)	2505 (53%)	61 (1%)	40 (1%)
2014	6213	2853 (46%)	3179 (51%)	79 (0%)	102 (0%)
Total	**21254**	**9352 (44%)**	**11158 (52%)**	**550 (3%)**	**194 (1%)**

Active filters
(1) Treatment type: IAPT. (2) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen. (3) Group by: Clinical Session - Psychotropic Medication Usage. (4) MDS / Non-MDS clinical contacts: MDS Clinical Sessions. (5) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (6) Complete vs Incomplete sessions: Show Complete Sessions only. (7) First session Date between: 01/01/2008 and: 31/12/2008 [2008 row]; 01/01/2009 and 31/12/2009 [2009 row]; 01/01/2010 and 31/12/2010 [2010 row]; 01/01/2011 and 31/12/2011 [2011 row]; 01/01/2012 and 31/12/2012 [2012 row]; 01/01/2013 and 31/12/2013 [2013 row]; 01/01/2014 and 31/12/2014 [2014 row].

Chi^2 (1) analysis of prescribed patients between years
2008-2009 = 0.13, p = 0.72; 2008-2010 = 0.06, p = 0.80; 2008-2011 = 0.50, p = 0.48; 2008-2012 = 1.41, p = 0.23; 2008-2013 = 1.66, p = 0.19; 2008-2014 = 2.16, p = 0.10; 2009-2010 = 0.05, p = 0.82; 2009-2011 = 0.50, p = 0.48; 2009-2012 = 3.21, p = 0.07; 2009-2013 = 4.21, p<0.05*; 2009-2014 = 8.25, p<0.005*; 2010-2011 = 1.13, p = 0.29; 2010-2012 = 5.54, p<0.05*; **2010-2013 = 7.21, p<0.01***; **2010-2014 = 13.54, p<0.001***; 2011-2012 = 1.50, p = 0.22; 2011-2013 = 2.34, p = 0.13; 2011-2014 = 6.36, p<0.05*; 2012-2013 = 0.09, p = 0.77; 2012-2014 = 1.97, p = 0.16; 2013-2014 = 1.36, p = 0.24.

Table 3. Adherence on entry, in total and by year

Year	N	Adherent (%)	Non-adherent (%)
2011	1036	1003 (97%)	33 (3%)
2012	1720	1525 (89%)	195 (11%)
2013	2148	1885 (88%)	263 (12%)
2014	2853	2497 (88%)	356 (12%)
Total	**7757**	**6910 (89%)**	**847 (11%)**

Active filters
(1) Treatment type: IAPT. (2) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen. (3) Group by: Clinical Session - Psychotropic Medication Usage. (4) MDS / Non-MDS clinical contacts: MDS Clinical Sessions. (5) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (6) Complete vs Incomplete sessions: Show Complete Sessions only. (7) First session Date between: 01/01/2011 and 31/12/2011 [2011 row]; 01/01/2012 and 31/12/2012 [2012 row]; 01/01/2013 and 31/12/2013 [2013 row]; 01/01/2014 and 31/12/2014 [2014 row].

Chi^2 (1) analysis of adherence between years
2011-2012 = 56.62, p<0.001*; **2011-2013 = 68.02, p<0.001***; **2011-2014 = 72.91, p<0.001***; 2012-2013 = 0.75, p = 0.38; 2012-2014 = 1.32, p = 0.25; 2013-2014 = 0.06, p = 0.80.

Table 4. Prescribed and non-prescribed patients on entry, by gender

Gender	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
Male	7210	3232 (45%)	3722 (52%)	181 (3%)	75 (1%)
Female	14038	6119 (44%)	7433 (53%)	367 (3%)	119 (1%)
Unknown	6	1 (17%)	3 (50%)	2 (33%)	0 0(%)
Total	**21254**	**9352 (44%)**	**11158 (52%)**	**550 (3%)**	**194 (1%)**

Active filters
(1) Treatment Type: IAPT. (2) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen. (3) First session Date between: 01/01/2008 and 31/12/2014. (4) Employment Attendance: MDS / Non-MDS clinical contacts. (5) MDS Clinical Sessions. (6) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (7) Employment Psychotropic Medication Usage. (8) Complete vs Incomplete sessions: Show Complete Sessions only. (9) Group by Demographics – Gender. (10) Group by Clinical Session - Psychotropic Medication Usage.

Chi^2 (1) analysis of gender
Male-female = 3.25, p = 0.07.

Table 5a. Age of prescribed and non-prescribed patients on entry by younger, middle-aged and older adults

Age	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
≤34	9592	3634 (38%)	5671 (59%)	212 (2%)	75 (1%)
35-64	10840	5414 (50%)	5020 (46%)	297 (3%)	109 (1%)
≥65	818	303 (37%)	464 (57%)	41 (5%)	10 (1%)
Total	**21250**	**9351 (44%)**	**11155 (52%)**	**550 (3%)**	**194 (1%)**

Table 5b. Age of prescribed and non-prescribed patients on entry, by ten year age ranges

Age	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
≤19	501	134 (27%)	354 (71%)	8 (2%)	5 (1%)
20-29	5799	2203 (38%)	3438 (59%)	114 (2%)	44 (1%)
30-39	5978	2443 (41%)	3331 (56%)	157 (3%)	47 (1%)
40-49	4680	2345 (50%)	2156 (46%)	130 (3%)	49 (1%)
50-59	2872	1614 (56%)	1149 (40%)	78 (3%)	31 (1%)
60-69	929	445 (48%)	435 (47%)	36 (4%)	13 (1%)
70-79	358	128 (36%)	207 (58%)	20 (6%)	3 (2%)
≥80	133	39 (29%)	85 (64%)	7 (5%)	2 (2%)
Total	**21250**	**9351 (44%)**	**11155 (52%)**	**550 (3%)**	**194 (1%)**

Active filters
(1) Treatment Type: IAPT. (2) MDS / Non-MDS clinical contacts. (3) MDS Clinical Sessions. (4) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (5) Employment Psychotropic Medication Usage. (6) Complete vs Incomplete sessions: Show Complete Sessions only. (7) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen; Employment Attendance. (8) Group by: Demographics - Age on Referral Date. (9) Group by: Clinical Session - Psychotropic Medication Usage. (10) First session Date between: 01/01/2008 and 31/12/2014.

Chi^2 (1) analysis of prescribed patients between young, middle-aged and older adults
Young-(middle-aged) = 326.31, p<0.0001*; young-older = 0.06, p = 0.81; **(middle-aged)-older = 43.85, p<0.0001***.

Chi^2 (1) analysis of prescribed patients between ten year age ranges
(≤19)-(20-29) = 25.59, p = 4.2e-7*; **(≤19)-(30-39) = 40.98, p<0.001***; **(≤19)-(40-49) = 106.93, p<0.001***; **(≤19)-(50-59) = 159.88, p<0.001***; **(≤19)-(60-69) = 68.68, p<0.001***; **(≤19)-(70-79) = 10.58, p<0.005***; (≤19)-(≥80) = 0.777, p = 0.38.
(20-29)-(30-39) = 12.54, p<0.001*; **(20-29)-(40-49) =172.27, p<0.001***; **(20-29)-(50-59) =280.44, p<0.001***; **(20-29)-(60-69) = 41.85, p<0.001***; (20-29)-(70-79) =0.01, p =0.76; (20-29)-(≥80) = 2,95, p = 0.09.
(30-39)-(40-49) = 97.40, p<0.001*; **(30-39)-(50-59) = 194.34, p<0.001***; **(30-39)-(60-69) = 21.20, p<0.001***; (30-39)-(70-79) = 2.19, p = 0.14; (30-39)-(≥80) = 5.87, p<0.05.
(40-49)-(50-59) = 27.535, p = 1.5e-7*; (40-49)-(60-69) = 0.69, p = 0.41; **(40-49)-(70-79) = 24.08, p = 9.3e-7**; **(40-49)-(≥80) = 20.60, p<0.001*.**
(**50-59)-(60-69) = 16.72, p<0.001***; **(50-59)-(70-79) = 49.56, p<0.001***; **(50-59)-(≥80) =35.25, p<0.001***.
(60-69)-(70-79) =14.87, p<0.001*; (60-69)-(≥80) = 15.91, **p<0.001*.**
(70-79)-(≥80) = 1.79, p = 0.18.

Table 6. Ethnicity of prescribed and non-prescribed patients on entry

Ethnicity	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
White	12948	6009 (46%)	6564 (51%)	293 (2%)	82 (1%)
Black	3039	1225 (40%)	1676 (55%)	103 (3%)	35 (1%)
Asian	676	260 (38%)	388 (57%)	17 (3%)	11 (2%)
Mixed	885	352 (40%)	506 (57%)	19 (2%)	8 (1%)
Other	854	344 (40%)	472 (55%)	30 (4%)	8 (1%)
Declined	208	79 (38%)	116 (56%)	12 (6%)	1 (0%)
DNK	28	11 (39%)	14 (50%)	0 (0%)	3 (11%)
Missing	2616	1072 (41%)	1422 (54%)	76 (3%)	46 (2%)
Total	**21254**	**9352 (44%)**	**11158 (52%)**	**550 (3%)**	**194 (1%)**

Active filters
(1) Treatment Type: IAPT. (2) MDS / Non-MDS clinical contacts: MDS Clinical Sessions. (3) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (4) Employment. (5) Psychotropic Medication Usage. (6) Complete vs Incomplete sessions: Show Complete Sessions only. (7) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen. (8) First session Date between: 01/01/2008 and 31/12/2014. (9) Group by: Demographics - Ethnic Group. (10) Group by: Clinical Session - Psychotropic Medication Usage.

Chi^2 (1) analysis of prescribed patients between ethnic groups
White-Black/Black British = 29.34, p = 6e-8*, **White-Asian/Asian British = 14.54, p <0.01***, **White-Mixed = 14.75, p <0.01***, **White-Other = 9.76, p <0.01***, Black-Asian/Asian British = 0.96, p = 0.33, Black-Mixed = 0.39, p = 0.53, Black-Other = 0.001, p = 0.98, Asian-Mixed = 0.13, p = 0.73, Asian-Other = 0.62, p = 0.43, Mixed-Other = 0.22, p = 0.64.

Table 7. Employment status of prescribed and non-prescribed patients on entry

Employment status	N	Prescribed (%)	Non-prescribed (%)	Declined (%)	DNK (%)
Employed FT	8233	3032 (37%)	4985 (61%)	163 (2%)	53 (1%)
Employed PT	2608	957 (37%)	1555 (60%)	74 (3%)	22 (1%)
Unemployed	4018	2046 (51%)	1800 (45%)	142 (4%)	30 (1%)
Student	1505	556 (37%)	912 (61%)	28 (2%)	9 (1%)
Retired	983	408 (42%)	518 (53%)	45 (5%)	12 (1%)
FT homemaker/carer	1183	508 (43%)	633 (54%)	33 (3%)	9 (1%)
LT sick/disabled	2410	1714 (71%)	627 (26%)	35 (1%)	34 (1%)
Unpaid volunteer	171	75 (44%)	90 (53%)	5 (3%)	1 (1%)
Declined to respond	139	54 (39%)	36 (26%)	26 (19%)	23 (17%)
Missing	9	3 (33%)	5 (56%)	0 (0%)	1 (11%)
Total	**21259**	**9353 (44%)**	**11161 (53%)**	**551 (3%)**	**194 (1%)**

Active Filters
(1) Treatment Type: IAPT. (2) MDS / Non-MDS clinical contacts: MDS Clinical Sessions. (3) IAPT Psychotropic Medication Usage: Prescribed and taking; Prescribed but not taking; Not Prescribed; Not stated (Person asked but declined to provide a response); Unknown (Person asked and does not know or is not sure). (4) Employment Psychotropic Medication

Usage. (5) Complete vs Incomplete sessions: Show Complete Sessions only. (5) IAPT Attendance: Attended on time or, if late, before the relevant CARE PROFESSIONAL was ready to see the PATIENT; Arrived late, after the relevant CARE PROFESSIONAL was ready to see the PATIENT, but was seen; Employment Attendance. (6) First session Date between: 01/01/2008 and 31/12/2014. (7) Group by: Clinical Session - Employment Status. (8) Group by: Clinical Session - Psychotropic Medication Usage.

Chi² (1) analysis of prescribed patients between employment status
Employed FT-Employed PT = 0.16, p = 0.80; **Employed FT-Unemployed = 251.07, p<0.001***; Employed FT-Student = 0.002, p = 0.96; **Employed FT-Retired = 13.66, p<0.001***; **Employed FT-FT homemaker/carer = 18.92, p<0.001***; **Employed FT-LT sick/disabled = 914.48, p<0.001***; **Employed FT-Unpaid volunteer = 4.00, p<0.05***.
Employed PT-Unemployed = 139.03, p<0.001*; Employed PT-Student = 0.02, p = 0.89; **Employed PT-Retired = 10.05, p<0.005***; **Employed PT-FT homemaker/carer = 13.49, p<0.001***; **Employed PT-LT sick/disabled = 603.95, p<0.001***; Employed PT-Unpaid volunteer = 3.54, p = 0.06.
Unemployed-Student = 99.83, p<0.001*; **Unemployed-Retired = 24.95, p = 5.9e-7*; Unemployed-FT homemaker/carer = 26.51, p = 2.6e-7***; **Unemployed-LT sick/disabled = 244.62, p<0.001***; Unemployed-Unpaid volunteer = 3.81, p = 0.05.
Student-Retired = 9.03, p<0.005*; **Student-FT homemaker/carer = 11.75, p<0.001***; **Student-LT sick/disabled = 468.01, p<0.001***; Student-Unpaid volunteer = 3.59, p = 0.06.
Retired-FT homemaker/carer = 0.04, p = 0.83; **Retired-LT sick/disabled = 247.78, p<0.001***; Retired-Unpaid volunteer = 0.11, p = 0.74.
FT homemaker/carer-LT sick/disabled = 273.52, p<0.001*; FT homemaker/carer-Unpaid volunteer = 0.05, p = 0.82.
LT sick/disabled-Unpaid volunteer = 58.16, p<0.001*.

Table 8. Medication status change matrix

		Medication status				
		Prescribed	**Non-prescribed**	**Declined**	**DNK**	**Total**
Medication status	**Prescribed**	4701 (33%)	1293 (9%)	173 (1%)	39 (0%)	**6206**
	Non-prescribed	906 (6%)	6354 (45%)	243 (2%)	29 (0%)	**7532**
	Declined	75 (1%)	168 (1%)	95 (1%)	5 (0%)	**343**
	DNK	42 (0%)	59 (0%)	4 (0%)	8 (0%)	**113**
	Total	**5724**	**7874**	**515**	**81**	**14194**

Active Filters
(1) Treatment type: IAPT. (2) Data field: Use of Psychotropic Medication. (3) IAPT Attendance: Attended on time, Arrived late but was seen. (4) Employment Attendance. (5) Complete vs Incomplete sessions: Show Complete Sessions only. (6) MDS / Non-MDS clinical contacts: MDS Clinical Sessions. (7) Session Start Date: 01/01/2008. (8) Session End Date: 31/12/2014

Table 9. Mean pre-/post-treatment scores and score changes for IAPT outcome measures

Measure	**Prescribed**				**Non-prescribed**			
	N	**Entry**	**Discharge**	**Change**	**N**	**Entry**	**Discharge**	**Change**
PHQ9	6650	16.08	11.82	-4.26	8502	12.26	8.53	-3.73
GAD7	6649	13.36	10.07	-3.29	8501	11.16	7.77	-3.39
WSAS	6645	19.71	15.95	-3.75	8498	15.42	11.85	-3.57

Active filters. (1) Treatment type: IAPT; (2) First session date: starting 1/1/08 and ending 31/12/14; (3) IAPT attendance: Attended on time or, if late was seen (4) MDS / Non-MDS clinical contacts: MDS Clinical Sessions (5) Complete vs Incomplete sessions: Show Complete Sessions only (6) Data field [PHQ9/GAD7/WSAS] (7) IAPT Psychotropic Medication Usage: Prescribed and taking, and Prescribed but not taking/Not Prescribed.